California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

NOTICE OF MEETING and AGENDA
Licensing Committee

DATE: **MARCH 7, 2007**
TIME: **10 a.m. – 1 p.m.**

Place: **Department of Consumer Affairs**
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento CA 95834

CONTACT PERSON:
VIRGINIA HEROLD
(916) 574-7911

This committee meeting is open to the public and will be held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Gloria Schultz (916) 574-7912, at least five working days before the meeting.

Opportunities are provided for public comment on each agenda item. Board members who are not on the committee may also attend and comment.

Note: Pharmacists and pharmacy technicians who attend the full committee meeting can be awarded two hours of CE, in accordance with the board's CE policy. A maximum of four CE hours can be earned each year by attending the meetings of two different board committees.

Call to Order 10 a.m.

1. Proposed Regulation Requirements for Pharmacies that Compound Medication -- Amendments to 16 CCR sections 1716.1 and 1716.2 and adoption of sections 1735 – 1735.8
2. Update: Request to Add the Exam for the Certification of Pharmacy Technicians Developed by the Institute for the Certification of Pharmacy Technicians as a Qualification Method for Pharmacy Technician Registration
3. California Schools of Pharmacy Proposal to Identify and Agree on the Professional Competencies that Should Be Achieved by the End of Basic Internship Experiences
4. Request by Pacific University of Oregon to Receive Board Recognition for Purposes of Issuing California Pharmacist Intern Licenses
5. Update: Disaster Response/California Department of Health Services -- Healthcare Surge Project
6. Legislative Proposals:
   (1) Renaming of the "Multistate Pharmacy Jurisprudence for California" to More Accurately Reflect Examination Content.
   (2) Establishment of State Protocol for Immunizations.
7. Request to Accept the Certification Examination of the Commission for Certification in Geriatric Pharmacy for Continuing Education Credit for Pharmacists
8. Update: Strategic Plan for 2007/08
9. Information: NABP Accredits Suppliers of Durable Medical Equipment
10. Competency Committee Report

Adjournment 1 p.m.

Meeting materials will be available from the board's Web site by March 2, 2007

Agenda Item 1

State of California Department of Consumer Affairs

Memorandum

To: **Licensing Committee** **Date: March 1, 2007**

From: **Board of Pharmacy**

Subject: **Compounding by Pharmacies**

At the January 2007 Board Meeting, the board moved to regulation hearing proposed regulations for pharmacies that compound medication, providing patient protections when they receive medication compounded by a pharmacy. These regulations were developed during 2004 while the board was convening its Work Group on Compounding with stakeholders and other regulatory agencies.

At the January Board Meeting, noting that some individuals may wish to comment on the regulations before they are noticed, the board also asked that those individuals with comments to provide these comments to the Licensing Committee by the end of February.

As of this date, comments have only been received from Dan Wills and joint comments from CPhA/Kaiser/and Dan Wills. These comments have been interspersed into the draft regulations that follow.

The committee needs to review these comments and determine if any of these items need to be incorporated into the regulation.

§1716.1. Compounding Unapproved Drugs for Prescriber Office Use.

As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:

(a) "Reasonable quantity" means that quantity of an unapproved drug which:

(1) is sufficient for that prescriber's office use consistent with the expiration date of the product as set forth in section 1716.2(a)(3); and

(2) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and

(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality and purity of the compounded medication.

(b) "Compounded medication" means medications actually compounded by the pharmacy supplying them to a prescriber.

(c) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4027, 4033, 4050, 4051, 4052, 4059, 4170 and 4171, Business and Professions Code.

§1716.2. Record Requirements--Compounding for Future Furnishing.

(a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:

(1) The date of preparation.

(2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.

(3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(4) The signature or initials of the pharmacist performing the compounding.

(5) A formula for the compounded product. The formula must be maintained in a readily retrievable form.

(6) The name(s) of the manufacturer(s) of the raw materials.

(7) The quantity in units of finished products or grams of raw materials.

(8) The package size and the number of units prepared.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4059, 4081 and 4332, Business and Professions Code.

CPHA: Comments with General Applicability:

1) The proposed language contains several references to either "expiration date" or "beyond use date." These references should be amended so that only one term is used, which, based on industry usage and trends, we believe should be "beyond use date."
2) There are several sections which require "written" documentation of some sort. These sections should be changed to "readily retrievable" in order to allow records to be kept electronically rather than require retention of paper documents.

Article 4.5 General Compounding

§1735. Definitions

(a) "Compounding" means any of the following activities occurring in a pharmacy pursuant to a prescription:
  (1) Altering the dosage form or delivery system of a drug
  (2) Altering the strength of a drug
  (3) Combining components or active ingredients

DENNIS MING: **into a drug product not commercially available**

  (4) Preparing a drug product from bulk chemicals

Compounding does not include the reconstitution of a drug pursuant to the manufacturer's direction for oral, rectal or topical administration.

Dan Wills: I notice that flavoring was taken out. I remember that being done since many of the chains are now flavoring. However, I have also heard stories by pharmacies that have had to fix problems associated with flavoring of meds by non-compounders. Most of the time it has to do with interactions of the flavoring agent or actually making the flavor worse. Do we want to re-look at this?

Compounding" means any of the following activities occurring in a pharmacy pursuant to a prescription *or in anticipation of a prescription based on past history*: I can't find anything that allows us to make preparations in a larger batch. This is sometimes needed for accuracy and safety, particularly when there is a very small dosage or therapeutic range. Business principles will stop people from making more than they will reasonably use. That would only incur waste. By putting past history in it, there would be an adjustment for the size of the operation. If a pharmacy only does one of these a week, they probably shouldn't make very much. If the demand is high however, and it can be proven historically, then a larger batch would make more sense. It also eliminates a regulatory punishment for success.

CPHA: (a) belongs in a separate section.

(b)"Integrity" means the drug will retain its effectiveness until the beyond use date noted on the label.

Dan Wills: "...will retain its **effectiveness**..." Aren't there cases where therapeutically a drug will become less effective even though it is still full strength? I would suggest changing to "...will retain it its *potency*..."

CPHA: change to: "Quality reviews required at appropriate steps in the preparation of the compounded preparation." Not all steps in the compounding process require qualtiy review.

(c) "Quality" means the drug is free of any contaminants and only contains those active ingredients indicated on the label.

Dan Wills: "...drug is free of **any** contaminants..." Should be changed to "*harmful levels*" or something similar. The air we breath has 100,000 contaminants in a cubic foot. Even sterile compounding laws allow us to have endotoxins as long as they are non-pyrogenic. Making something free of any contaminants is impossible.

(d) "Strength" means the amount of active ingredient in each unit of the drug.

(e) As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:

(1) "Reasonable quantity" means that quantity of an unapproved drug which:

(A) is sufficient for that prescriber's office use; and

(B) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and

(C) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for strength, quality and integrity of the compounded medication.

(2) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.[1]

CPHA: (e) Eliminate the word "stability" before "studies" in the third line. The expense of a formal "stability study" is not an appropriate requirement; what is needed is some form of study that supports an extended beyond use date for a compounded drug product.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, and 4052, Business and Professions Code.

§1735.1. Requirements

(a) Prior to compounding a drug, the dispensing pharmacist shall establish a professional relationship with the prescriber and patient.

Dan Wills: "...pharmacist shall establish a **professional relationship,** *as evidenced by a valid prescription,* with the prescriber and patient." Does a prescription constitute a professional relationship? If not, this would be difficult to define. Would it mean a phone call? A personal visit? Taking them out to dinner? If a prescription is not good enough, we are being held to a higher standard than other pharmacists. When a prescription is brought in by the patient, or transmitted from a doctor, there is no question of a relationship. There is just an implied relationship and it is just filled. Also, this wording puts the burden on the pharmacist to create the relationship. What if a veterinarian who we have not met, calls us and prescribes for Fluffy who we have also never had an interaction with? What would need to be done? If anything more than a valid prescription is required to "establish a relationship," we will hurt many patients in rural areas who do not have immediate access to the pharmacy.

(b) A drug may not be compounded without a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.
(2) Inactive ingredients to be used.
(3) Process and/or procedure used to prepare the drug.
(4) Quality reviews required at each step in preparation of the drug.

Dan Wills: "...quality reviews at each *appropriate* step in the preparation." This allows for professional judgment.

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[1] Moved from 1716.1

(5) Post compounding process or procedures required, if any.
(6) Beyond use dating requirements.

(c) The pharmacist shall be responsible for assuring that the compounded drug retains its strength, quality, and integrity until dispensed.

(d) All chemicals, drug products, and components must be used and stored according to compendial and other applicable requirements to maintain their strength, quality and integrity.

(e) The beyond use date of the finished product must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies of drugs using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

Dan Wills: ".. supported by **stability studies**..." Can we change this to "...supported by stability *and/*or *potency studies*...?" Recently there has been a lot of talk about this subject on the IJPC network as well as with testing labs. A stability study will costs thousands of dollars to find out all the degradants (sp?) in the medicine. Currently when we send something in for testing, we will check for potency and if appropriate sterility and pyrogenicity. I know that stability studies would be better, but if a capsule we make still tests out to be just as potent in one year as on day one, why not put that on the container? Especially if the bulk powder doesn't expire for 10 years. Stability studies are used in manufacturing. They are not standard procedure in compounding. We need to start gathering stability studies from the entire industry, but That will be a slow process. If potency is good at day one, why not OK at day 365?

We have a doctor that invented a vitamin B5/B6 cream. After a couple of weeks it oxidizes. He has had it tested, and found it to be just as potent as far as the vitamin is concerned and it still works for his patients. However, the drug is not stable, because of the oxidization. Here is a case where it would fail stability, yet be therapeutically effective. Isn't that the real issue? By adding potency to the regulations we eliminate the "pull it out of the air" approach, can have some scientific basis for a date, yet allow for professional judgment. Isn't that what you paid the big bucks at school for?

~~(f) A pharmacy may contract with another pharmacy to compound drug products, pursuant to a prescription, for delivery to another pharmacy. The compounded product must be labeled with the name of the pharmacy that compounded the drug and the information required by Business and Professions Code Section 4076.~~

(g) Pharmacists who compound drugs, or supervise the compounding of drugs, shall be responsible for ensuring that the compounded drug has been prepared, labeled, stored, and delivered properly.

(h) Prior to allowing any drug to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board (form XXXXX). The self assessment shall subsequently be performed before July 1 of each year, within 30 days of the designation of a new pharmacist-in-charge, or within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4052, and 4076, Business and Professions Code.

§1735.2. Records

(a) For each compounded drug a record shall be made that includes at least the following elements:

(1) The information required of a master formula record.
(2) The date the drug was compounded.
(3) The identity of the pharmacy personnel who compounded the drug.
(4) The identity of the pharmacist reviewing the final product.
(5) The quantity of each component used compounding a drug.
(6) The supplier and lot number of each component.
(7) The equipment used compounding a drug.

CPhA: More detail is needed on what "equipment used" really should include.

(8) The internal reference (lot) number.
(9) The expiration date of the final drug.

Dan Wills: **Expiration date** should be changed to *beyond use date*. It will then match 1735.1 (e) as well as be current with emerging industry vocabulary. Expiration dates are used for manufactured drugs and beyond use dates for compounds. (This would also be a reason to add potency in the paragraph above.

(10) The quantity or amount of drug product compounded.

(b) Pharmacies must maintain records of the acquisition, storage, and proper destruction of chemicals, drug products, and components used in compounding.

(c) The chemicals, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall maintain certificates of purity or analysis for components, chemicals, or drug products used in compounding. Certificates of purity or analysis are not required for drugs used in compounding that are approved by the Food and Drug Administration.

Dan Wills: "The pharmacy shall maintain certificates of purity or analysis for **components, chemicals, or drug products used in compounding**." Certificates of analysis cannot be obtained for sugar purchased at the grocery store. Somebody came up with a good alternative wording a couple years ago, but I can't remember what it was. Was it limited to active ingredients? Also, I would like to be able to have the C of A's accessible by computer. PCCA has them all online to be checked. We are told by OSHA that this method is OK for MSDS sheets. Let's make it OK for C of A's.

"Certificates of purity or analysis are not required for *Food and Drug Administration approved manufactured* drugs used in compounding." An example of the difference in wording is that we use ketoprofen powder which is an FDA approved drug from an FDA approved facility. As the

sentence currently reads, we may not be required to maintain a C of A for that. I believe this change meets the spirit of what was desired.

CPHA: "Certificates of purity or analysis are not required for components used in compounding that are approved by the Federal Food and Drug Administration." An important consideration here is to either include or exempt foods, food colorings, flavorings or other components that are not subject to the drug approval process.

(d) Pharmacies must prepare, maintain, and retain all records required by this article in the pharmacy in a readily retrievable form for a period of three years from the date the record was created.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005 Business and Professions Code.

§1735.3. Labeling

(a) In addition to labeling information required under Business and Professions Code Section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active component(s).

(b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.

(c) Drugs compounded into unit-dose containers shall be labeled with the name of the active component, concentration or strength, volume or weight, and an expiration date.

Dan Wills: Again change **expiration date** to *beyond use date.*

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005 and 4076, Business and Professions Code.

§1735.4. Policies and Procedures

(a) Pharmacies must maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures for the pharmacy.

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge.

(c) Provisions to notify the staff assigned compounding duties of any changes in the policy and procedure manual must also be included.

(d) The policy and procedure manual shall include written documentation of a plan for the recall of dispensed compounded products where subsequent verification demonstrates the potential for adverse effects with continued use of the compounded drug.

(e) Written processes used to maintain, store, calibrate, clean/disinfect equipment used in compounding drug shall be contained in the policy and procedure manual and shall be incorporated as part of the staff training and competency evaluation process.

Dan Wills: Written processes **used** to maintain, ..." change to "Written processes *outlining how* to maintain, ..." Written processes aren't the too used to do the maintaining, etc.

(f) The pharmacist-in-charge shall establish policies and procedures to ensure that compounded drugs have the strength indicated by the label.

CPHA: Pharmacies must maintain a readily retrievable policy and procedure manual for compounding activities that includes at least:

(a) Procurement procedures for components used in compounding;
(b) Methods for the determining formulations and compounding processes for drug products;
(c) Requirements for general cleaning and maintenance of facilities and equipment;
(d) Standard operating procedures for the pharmacy;
(e) Procedures for recalling dispensed compounded products;
(f) Procedures for maintenance, storage, calibration, cleaning and disinfecting equipment used in compounding drug products;
(g) Steps used to ensure that compounded drugs products have their labeled strength, consistent with standards for the profession;
(h) Methods to notify the staff assigned to compounding dutes of any changes in the policy and procedure manual.

The policy and procedure manual shall be reviewed annually by the pharmacist-in-charge.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005 and 4113, Business and Professions Code.

§1735.5. Facilities and Equipment

(a) Pharmacies shall provide written documentation of facilities and equipment necessary for the safe and accurate compounding of a drug, to also include, where applicable, certification of the facility/equipment.

Dan Wills: "Pharmacies shall provide **written documentation of facilities and equipment** necessary for the safe..." How do you document a facility? Perhaps it would be better stated, "*Where applicable, pharmacies shall provide documentation that the facilities and equipment will function as* necessary for the safe..."

(b) Equipment shall be stored, used, and maintained in accordance with manufacturers' specifications.

(c) Equipment used in compounding drug products shall be calibrated prior to use to ensure accuracy. Documentation of calibration shall be recorded in writing.

Dan Wills: "Documentation of calibration shall be recorded *and maintained.*" Some people like to maintain these records on a computer instead of **in writing**.

CPhA: (a) Requires clarification. The use of the word "documentation" here is confusing. What needs to be documented or what sort of documentation is needed?

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

§1735.6. Training of Staff, Patient and Caregiver

(a) Pharmacies shall maintain written documentation that pharmacy personnel have the skills and training required to correctly perform their assigned responsibilities relating to compounding.

(b) The training of pharmacy personnel shall be documented and retained as part of an on-going competency evaluation process for pharmacy personnel involved in compounding.

CPHA: Add at the end of subsection (b): The ongoing training and competency evaluation process shall include the procedures for maintenance, storage, calibration, cleaning and disinfecting of equipment used in compounding drug products.

(c) Pharmacy personnel assigned compounding duties shall demonstrate knowledge about the processes and procedures used to compound drug drugs prior to compounding any drug.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

§1735.7. Quality Assurance

(a) Pharmacies shall provide written documentation of the development of and adherence to a quality assurance plan.

Dan Wills: Pharmacies shall provide documentation of *the* adherence to a quality assurance plan." Do we really need to document **the development** of one?

CPhA: (a) eliminate "the development of and" There's no need to provide documentation of the development of a QA plan. The existence of one is sufficient documentation of whatever is intended here.

(b) The quality assurance plan shall include verification, monitoring, and review of the adequacy of the compounding process and shall include documentation of that review by the assigned personnel to demonstrate the compounded drug meets the specified criteria of strength and quality.

(c) As part of the quality assurance plan, all qualitative/quantitative analysis reports for compounded drug drugs shall be retained and collated with the compounding record and master formula.

(d) The quality assurance plan shall also include a written process that describes and documents the action taken when a compounded drug fails to meet the minimum standards for quality, strength and integrity.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

Agenda Item 2

State of California Department of Consumer Affairs

Memorandum

To: **Licensing Committee** **Date: March 1, 2007**

From: **Board of Pharmacy**

Subject: **Exam for the Certification of Pharmacy Technicians (ExCPT)**

There has been no action on this project since the October Board Meeting, when the board directed that a review of the ExCPT exam take place. I had hoped that the Department of Consumer Affairs would soon hire a new PhD psychometric expert to head their Office of Examination Resources, who could assist the board in performing this review. This has not occurred and the department is having a difficult time with recruitment.

Section 139 of the Business and Professions Code requires a periodic assessment of all licensure examinations used by a regulatory agency for job-relatedness. Discussions are currently underway between the board and departmental staff on establishing a method to initiate a review of the ExCPT exam, as well as the PTCB.

Provided below is information provided to the committee at the December Licensing Committee

Background:

In California, individuals may become qualified for registration as pharmacy technicians by one of four means:

1. Possessing an associate's degree in pharmacy technology.
2. Completing a course of training specified by the board in regulations (accredited by ASHP, provided by the armed forces, or at least 240 hours of instruction covering specific topics).
3. Graduating from a school of pharmacy recognized by the board.
4. Being certified by the Pharmacy Technician Certification Board.

In September the Licensing Committee began a discussion regarding another pharmacy technician examination, the Exam for the Certification of Pharmacy Technicians (ExCPT). This exam has been developed by the Institute for the Certification of Pharmacy Technicians.

This examination is accepted by Connecticut, New Jersey, Minnesota, Oregon and Virginia as a qualifying route for registration for pharmacy technicians. According to material provided by the institute, the exam is a computer-based exam, which is administered in 700 locations nationwide. The National Community Pharmacists Association and the National Association of Chain

Drug stores support use of the exam.

The committee requested staff to initiate a review of the ExCPT, and whether the examination is job related and has been validated as required by California Business and Professions Code section 139.

To use the ExCPT exam as a qualifying method for pharmacy technician licensure, the either a statutory or regulation amendment needs to be adopted. The board should not proceed until this review is completed.

Within the Department of Consumer Affairs, is the Office of Examination Resources. This office provides examination and psychometric services to professional and vocational licensing boards in the department. At the current time, this office is undergoing recruitment for a chief. Until such time as a new chief is hired, the board probably should not initiate a review of the ExCPT examination using this office.

The board could also contract for an expert to conduct this review, or require the vendor of the ExCPT to use a board-selected designated expert to conduct the review with the results going to the board.

The board has received comments from those who support the continued sole use of the PTCB examination, that the new ExCPT exam must be psychometrically sound and assessed.

139. (a) The Legislature finds and declares that occupational analyses and examination validation studies are fundamental components of licensure programs. It is the intent of the Legislature that the policy developed by the department pursuant to subdivision (b) be used by the fiscal, policy, and sunset review committees of the Legislature in their annual reviews of these boards, programs, and bureaus.

(b) Notwithstanding any other provision of law, the department shall develop, in consultation with the boards, programs, bureaus, and divisions under its jurisdiction, and the Osteopathic Medical Board of California and the State Board of Chiropractic Examiners, a policy regarding examination development and validation, and occupational analysis. The department shall finalize and distribute this policy by September 30, 1999, to each of the boards, programs, bureaus, and divisions under its jurisdiction and to the Osteopathic Medical Board of California and the State Board of Chiropractic Examiners. This policy shall be submitted in draft form at least 30 days prior to that date to the appropriate fiscal, policy, and sunset review committees of the Legislature for review. This policy shall address, but shall not be limited to, the following issues:

(1) An appropriate schedule for examination validation and occupational analyses, and circumstances under which more frequent reviews are appropriate.

(2) Minimum requirements for psychometrically sound examination validation, examination development, and occupational analyses, including standards for sufficient number of test items.

(3) Standards for review of state and national examinations.

(4) Setting of passing standards.

(5) Appropriate funding sources for examination validations and occupational analyses.

(6) Conditions under which boards, programs, and bureaus should use internal and external entities to conduct these reviews.

(7) Standards for determining appropriate costs of reviews of different types of examinations, measured in terms of hours required.

(8) Conditions under which it is appropriate to fund permanent and

limited term positions within a board, program, or bureau to manage these reviews.

(c) Every regulatory board and bureau, as defined in Section 22, and every program and bureau administered by the department, the Osteopathic Medical Board of California, and the State Board of Chiropractic Examiners, shall submit to the director on or before December 1, 1999, and on or before December 1 of each subsequent year, its method for ensuring that every licensing examination administered by or pursuant to contract with the board is subject to periodic evaluation. The evaluation shall include (1) a description of the occupational analysis serving as the basis for the examination; (2) sufficient item analysis data to permit a psychometric evaluation of the items; (3) an assessment of the appropriateness of prerequisites for admittance to the examination; and (4) an estimate of the costs and personnel required to perform these functions. The evaluation shall be revised and a new evaluation submitted to the director whenever, in the judgment of the board, program, or bureau, there is a substantial change in the examination or the prerequisites for admittance to the examination.

(d) The evaluation may be conducted by the board, program, or bureau, the Office of Examination Resources of the department, the Osteopathic Medical Board of California, or the State Board of Chiropractic Examiners or pursuant to a contract with a qualified private testing firm. A board, program, or bureau that provides for development or administration of a licensing examination pursuant to contract with a public or private entity may rely on an occupational analysis or item analysis conducted by that entity. The department shall compile this information, along with a schedule specifying when examination validations and occupational analyses shall be performed, and submit it to the appropriate fiscal, policy, and sunset review committees of the Legislature by September 30 of each year. It is the intent of the Legislature that the method specified in this report be consistent with the policy developed by the department pursuant to subdivision (b).

Agenda Item 3

State of California Department of Consumer Affairs

Memorandum

To: **Licensing Committee** **Date: March 1, 2007**

From: **Board of Pharmacy**

Subject: **Pharmacist Intern Competencies**

The Board of Pharmacy has voted to join in a project initiated by California's schools of pharmacy, who are working together with other stakeholders to evaluate the components of ACPE approved intern experience at both the basic (IPPE) and advanced (APPE) levels. The project is called the California Pharmacy IPPE/OSCE Initiative. The goal is to develop an alternative component to assessing intern experience.

The California pharmacy schools are collaborating on this new initiative to determine and assess the competencies that students should achieve by the end of their introductory pharmacy practice experiences (IPPEs) prior to starting their advanced pharmacy practice experiences (APPEs). This initiative is in response to new ACPE accreditation standards that spell out how much time students must spend in IPPEs and APPEs rather than what they should learn (outcomes). The ACPE believes that there should be 300 hours of this basic experience.

Two day-long meetings have taken place so far – January 26 and February 28 0During the first phase of the project, the committee will determine the competencies that students should achieve. One item they will use is the old Board of Pharmacy Intern Affidavits as a starting point. The second phase involves developing a reliable and valid performance-based exam (i.e., objective structured clinical exam, OSCE) to assess student achievement of these competencies.

At this Licensing Committee Meeting, Barbara Sauer, PharmD, of UCSF's School of Pharmacy will provide information about what this group will evaluate and hopes to accomplish. Details about the initiative are provided in this tab section.

President Powers has appointed Board Member Susan Ravnan as the board's representative to this group.

One concern of the group is that requiring a specific duration of experience (i.e., 1,500 intern experience hours) but without specifying the components to be gained from the experience is not beneficial.

The goals of the initiative are to:

1. Reach consensus on the basic foundational competencies that all pharmacy students in California should master during basic intern experiences.
2. Train faculty members from each pharmacy school in California how to develop and administer an OSCE-based assessment.
3. Develop a validated and standardized OSCE-based examination to assess

achievement of the basic competencies

4. Develop a mechanism to assure replenishment of the OSCEs and exam security in the future
5. Petition ACPE to accept an OSCE-based assessment for basic experience as evidence of compliance with specific ACPE standards.

The timeline aims for incorporation of the standards during academic year 2007-08.

California Pharmacy IPPE-OSCE Initiative Meeting
Jan. 23, 2007, 10AM – 3PM
UCSF Faculty Alumni House

Attendees:
Barbara Sauer, UCSF (Co-Chair)

Kathy Besinque, USC (Co-Chair)
Eric Boyce, UOP (Co-Chair)

Sarang Aranke, Target
Elizabeth Boyd, UCSF
James Colbert, UCSD
Robin Corelli, UCSF
William Gong, USC
Steven Gray, Kaiser
Gamal Hussein, Loma Linda University
Paul Lofholm, CPhA
Susan Ravnan, UOP
Debra Sasaki-Hill, Touro University
Sam Shimomura, Western University
Anne Sodergren, CA State Board of Pharmacy
Rick Sylvies, Western University
Reza Taheri, Loma Linda University
Dianne Tobias, Tobias Consulting Services
Dave Williams, Safeway
Annie Wong-Beringer, USC
Sharon Youmans, UCSF
Keith Yoshizuka, Touro University

Unable to Attend:
Sian Carr-Lopez, UOP
Jeff Goad, USC
Kelli Haase, CSHP
Virginia Herold, CA State Board of Pharmacy
Robert Ignoffo, CSHP
Marilyn Shreve, Astra Zeneca

Action Items Before Next Meeting

1. Review draft minutes and submit any corrections to Barbara.
2. **Between now and the next meeting, each group should work on it's own statements to complete the list.** Are there any gaps, overlaps or inconsistencies? Are the statements prioritized?
3. Edit the statements to be consistent in language and written in **measurable** terms.
4. Send your revisions to Barbara **by February 23.**

Date/Location/Time of Next Meeting: Tuesday, February 23, 2007 at USC, 10AM-3PM

1. Welcome and Introductions

Mary Anne Koda-Kimble, dean of the UCSF School of Pharmacy welcomed those in attendance. She presented an overview of how the initiative got started and the widespread support that it was receiving. Following her remarks, members of the group introduced each other, describing their positions and reasons for participation.

2. Background and Goals

Barbara Sauer presented an overview of the project goals and process planned to accomplish these goals. She described experiential education in terms of what the schools supervise (IPPEs through APPEs, now 30% of the curriculum) and what the State Board oversees (Internship, 1500 hours). She concluded with a review of the agenda for this meeting and some things to keep in mind when defining the IPPE-APPE interface. Mary Anne suggested adding another goal, a scholarly evaluation of the project.

Eric Boyce followed with an overview of the new ACPE accreditation standards and guidelines pertaining to IPPEs. He described the changes that had been made to the previous document, including the philosophy behind those changes and the new areas of emphasis. He reviewed the language pertaining to IPPEs (Standards 10, 14; Guideline 14.4; Appendix C), as well as the primary modes of assessment and evaluation. He concluded with some tips for writing competency statements in behavioral and measurable terms. A handout summarizing the latter was distributed to each of the work groups.

Kathy Besinque presented the results of a survey distributed to representatives from each of the California schools prior to the meeting. All of the schools provide IPPEs as part of one or more didactic courses. All provide experiences in community pharmacies and 6/7 provide experiences in hospital/institutional pharmacies. In general, community experiences preceded hospital experiences. Schools varied in which experiences were required, which professional year the different IPPEs were offered, and how many hours were devoted to various types of experiences. The main concerns expressed were finding time in the curriculum and having an adequate number of sites to meet the "300 hour" requirement. A summary of the results, including breakdown by school, was distributed.

3. School Presentations

Representatives from each of the school presented a brief overview of their current and proposed IPPEs. It was clear from the presentations and survey results that schools varied in their views of the purpose of IPPEs and thus the types of activities included.

4. General discussion

- Logistics of the OSCE, including when and where they would they be done, and at which schools.
- Psychometric evaluation to assure reliability and validation is necessary, as is exam security.
- School's might need some flexibility so that the OSCE is scheduled after most IPPEs, yet allows flexibility to accommodate scheduling of APPEs.
- OSCEs are resource-intensive, there might need to be a written component as well.
- The above topics and other issues surrounding the OSCE component will be determined at the June and August conferences with Zubin Austin.

5. Break Out Groups

Barbara facilitated a discussion of potential topics for the breakout groups. Originally, 3-4 groups were planned, with 2 of the groups assigned to community practice and hospital/institutional practice. The 3rd and 4th groups could either focus on other practice settings or overarching competencies, such as communications and/or professionalism. After discussion, participants decided to have all 4 groups work on essential functions:

Agenda Item 4

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: Licensing Committee Date: March 1, 2007

From: Board of Pharmacy

Subject: Pacific University School of Pharmacy

The Pacific University School of Pharmacy is requesting that the Board of Pharmacy recognize its school of pharmacy for purposes of approving intern applications.

Current regulation, 16 CCR section 1719, states that a "recognized school of pharmacy" means a school accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education (ACPE).

Pacific University School of Pharmacy is in precandidate status, but is proceeding toward eligibility to candidate accreditation status.

According to the ACPE, its Board of Directors will make a decision on the status of Pacific University School of Pharmacy in June 2007 with information available to the general public in mid-July. A program that achieves candidate accreditation status can remain in this status from 2-4 years before advancing to full accreditation status. Historically, pharmacy programs that advance to candidate status do achieve full accreditation status, but ACPE cannot guarantee that any particular school will do so in the future.

Attached is the request from the Pacific University School of Pharmacy requesting recognition by the board.

PACIFIC
UNIVERSITY
1849
OREGON

School of Pharmacy
222 SE 8th Ave., Suite 451
Hillsboro, OR 97123
Phone (503) 352-7283 • Fax (503) 352-7270
Website: http://www.pacificu.edu/pharmd/

January 12, 2007

California State Board of Pharmacy
Virginia Herold, Interim Executive Officer
1625 N Market Blvd., N219
Sacramento, CA 95834

Dear Board of Pharmacy,

This letter formally requests recognition of the Pharm. D. Program of Pacific University School of Pharmacy by the Board of Pharmacy of the State of California.

Pacific University School of Pharmacy was granted Pre-Candidate status in June, 2006 and matriculated its inaugural class the following August. Our students undergo experiential training throughout their curriculum and it is expected that a number of them will undertake pharmacy practice rotations in diverse locales around the national beginning in June, 2007.

We look forward to hearing from you at your earliest possible convenience. Please do not hesitate to contact me with any questions.

Yours truly,

Susan M. Stein, M.S., R.Ph.
Assistant Dean for Clinical Programs and Student Development
Pacific University, School of Pharmacy
222 SE 8th Ave., Suite 451
Hillsboro, OR 97123
(503) 352-7285
steins@pacificu.edu

Agenda Item 5

State of California Department of Consumer Affairs

Memorandum

To: **Licensing Committee** **Date: March 1, 2007**

From: **Board of Pharmacy**

Subject: **Emergency Preparedness for California**

At the October Board Meeting, the board amended and approved a general policy statement that outlines its expectations for how disaster response in California may proceed. This policy statement is on the board's Web site and was published in the January 2007 *The Script.*

This week and next, the state is hosting a conference for state agencies on disaster preparedness. Several inspectors from the board are attending the conference. Here is the schedule for these seven days of training:

February 27-March 1: Surge Response
March 5-6: Standards and Liability
March 8-9: Reimbursement

I am attaching the pre-meeting materials.

Inspector Ralph Orlandella attended the three-day "Surge Response" session, and Chairperson Conroy was able to attend the March 1 session. At our meeting, Inspector Orlandella will provide information about the training, as will Chairperson Conroy.

A fuller presentation is anticipated for the April Board Meeting.

State of California—Health and Human Services Agency
California Department of Health Services

SANDRA SHEWRY
Director

ARNOLD SCHWARZENEGGER
Governor

January 30, 2007

Dear Stakeholder:

I am writing to ask you to participate in an important initiative to help California's healthcare system prepare for a major disaster that could lead to a significantly increased demand for medical services.

Providing healthcare during a large-scale public health emergency presents significant challenges for healthcare facilities, licensed healthcare professionals, local health departments, and communities. During emergency events, healthcare systems must convert quickly from their existing patient capacity to "surge capacity" - a significant increase beyond usual capacity - to rapidly respond to the needs of affected individuals. The demands of a sustained or catastrophic emergency may prevent operating in accordance with existing healthcare standards. While California has healthcare standards for use during normal conditions, it is essential that California provide guidance with regard to the standards likely to be in effect during sustained emergency operations. This guidance should address professional standards of practice, facility operations, liability of hospitals and professionals, reimbursement of care, and standards for operations of alternate care sites. California is the first state to address surge planning in this manner.

The California Department of Health Services (CDHS) has contracted with PricewaterhouseCoopers, an international consulting firm, in an aggressive six-month project to address this challenge. The goal of this project is to provide the following:

- A standards and guidelines manual that addresses the existing statutes and regulations that currently govern the standards of care, and identifies those that may be flexed or waived during a declared emergency;
- Operational tools that will guide healthcare planners in the adoption and implementation of new temporary standards; and
- A training curriculum to support the planning and preparation for optimal surge response.

The success of this project depends on your involvement and that of other stakeholders to satisfactorily address issues and possible impediments to planning for the optimal surge response. We invite you to help address the complex issues of surge planning by actively participating in three Collaborative

Design Sessions. The Collaborative Design Sessions will be multi-day working sessions during which participants will identify the complex issues and gaps in current preparedness efforts with regard to the various aspects of surge planning. Resolution of gaps and issues identified at the Collaborative Design Sessions will take place in smaller workgroups that will be formed and convene after completion of the sessions.

1501 Capitol Avenue, Suite 6001, MS 0000 • P.O. Box 997413 • Sacramento, CA 95899-7413
(916) 440-7400 • (916) 440-7404 FAX • Internet address: www.dhs.ca.gov

The first Collaborative Design Session, focused on the operational aspects of surge planning – beds, facilities, labor, supplies, and equipment – will be a three-day session held from February 27 to March 1, 2007 in San Jose. The second Collaborative Design Session, focused on standards, guidelines and liability, will be a two-day session held on March 5 and 6, 2007 in Los Angeles. The third Collaborative Design Session, focused on reimbursement, will be a two-day session held on March 8 and 9, 2007 in Los Angeles. We anticipate approximately 100 participants for each Collaborative Design Session. If the number of participants registered for any session exceeds available space, we will implement a process of selection to determine the final attendees to the sessions. All interested stakeholders will be able to participate in the workgroups formed to resolve the issues and gaps identified in the Collaborative Design Sessions.

The enclosed materials provide a more detailed description of how CDHS and PricewaterhouseCoopers have organized this project and how you can participate. These materials are also available on our website at http://www.dhs.ca.gov/epo/surge

I actively encourage you and/or your organization to join us. You can indicate your interest in participating in one or more of the Collaborative Design Sessions, the workgroups, or being informed of progress throughout the project by registering on our website or by calling PricewaterhouseCoopers at (213) 217-3900. All registration will occur through this process.

On February 5 and February 8, 2007, we will hold one-hour teleconference sessions at 11 am to provide an overview of the project. The teleconference dial-in number for February 5 is (888) 801-1508, the access code is 861511. The dial-in number for February 8 is (888) 801-1513, the access code is 861512. If you have any questions about this letter, please feel free to contact Ted Selby in CDHS' Emergency Preparedness Office at (916) 650-6416.

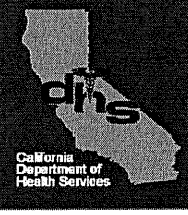
I thank you in advance and look forward to collaborating with you in this important project.

Sincerely,

Sandra Shewry

Sandra Shewry
Director

Enclosures

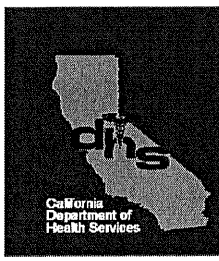


Development of Standards and Guidelines for Healthcare Surge during Emergencies

Stakeholder Orientation

Development of Standards and Guidelines for Healthcare Surge during Emergencies

Table of Contents



Development of Standards and Guidelines for Healthcare Surge during Emergencies

A. Background

Providing healthcare during a large scale public health emergency presents significant challenges for healthcare facilities, licensed healthcare professionals, and communities. During emergency events, healthcare systems must convert quickly from their existing patient capacity to "surge capacity" - a significant increase beyond usual capacity - to rapidly respond to the needs of affected individuals.

The demands of the emergency may prevent compliance with the existing healthcare standards. Just as California has healthcare standards for use with a normal operations, it is essential that California provide guidelines that identify the extent to which existing standards can be flexed or waived for healthcare delivery during emergencies. In order to assist healthcare providers to successfully plan for a healthcare surge, and as part of Governor Schwarzenegger's 2006 Surge Initiative, the California Department of Health Services (CDHS) has launched a project to address the issues of surge capacity during an emergency.

In February 2006, CDHS conducted the California Hospital Surge Capacity Survey, a statewide survey to assess healthcare surge capacity among Health Resources and Services Agency (HRSA) participants. The survey indicated that many California hospitals lack planning and resources needed to treat patients during emergencies that require significant or sustained surge and local health departments do not have the capacity to augment healthcare resources. Recognizing the importance and urgency of the problem, the State Budget Act for fiscal year 2006-2007 authorized CDHS to develop standards and guidelines to address the issues of surge capacity during an emergency.

Surge planning for the healthcare system is a substantial and complex challenge. In a time of significant disaster, a successful plan must predict and provide flexible arrangements to address capacity (volumes of patients) and capabilities (types of illnesses) that emerge above baseline requirements. The issues that need to be addressed are diverse and include:

- Standards of practice during an emergency
- Liability of hospitals and licensed healthcare professionals
- Reimbursement of care provided during an emergency
- Operating alternate care sites
- Surge capacity operating plans at individual hospitals

The deliverables for this project are intended to help every local healthcare provider, local health department, and community in California plan and put into operation a surge response to major disasters.

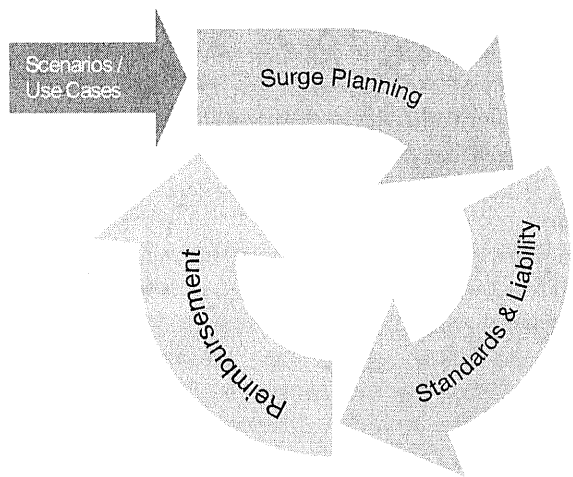
B. Approach

CDHS has contracted with PricewaterhouseCoopers LLP (PwC), an international consulting firm with a large US-based healthcare practice, to undertake this initiative in an aggressive six month period. PwC helped to create the post-Katrina blueprint for the recovery of the Louisiana healthcare system with resources that included physicians, nurses, healthcare planners, operating executives, standards and reimbursement experts, and experienced support staff.

The project approach is to assess the healthcare system's ability to surge using realistic examples of patients making their way through the delivery system during a significant disaster. This 'use case' methodology is a common way to evaluate experiences in complex and fragmented environments.

In consultation with subject matter experts, the project team will develop five patient profiles that will be used in three disaster scenarios that account for the vast majority of delivery challenges likely to be encountered in a surge environment during significant disasters. These 15 use cases will be used to identify planning gaps. In Collaborative Design Sessions, stakeholders will identify the challenges, barriers, and gaps in care faced by each of the patients in each disaster scenario. To effectively resolve these gaps, issues will be consolidated into three initiatives, each addressed in a separate Collaborative Design Session:

1. Surge planning (facilities including alternate care sites, equipment and supplies, and labor);
2. Standards and Liability; and
3. Reimbursement.



B. Approach (continued)

The project will begin by soliciting California stakeholders to participate in Collaborative Design Sessions. These intensively facilitated group activities use the collaboration of participants to surface and solve problems. For this project, stakeholders, based on their skill sets, will be asked to contribute their time to one of the three initiative areas. The Collaborative Design Sessions will address in sequence the three initiatives of Surge Planning, Standards and Liability, and Reimbursement. Each Collaborative Design Session will be two to three days in duration and is expected to include stakeholder participants with the relevant skills and experiences. The participants' task will be to analyze the 15 use cases for the purpose of identifying issues that could present impediments to the optimal surge environment. The issues that are identified in the first Collaborative Design Session (Surge Planning) will be included in the second Collaborative Design Session (Standards & Liability), and the combination of these issues will be included in the third Collaborative Design Session (Reimbursement). The overall goal of the three sessions will be to identify, assess, and prioritize as many issues as possible.

At the conclusion of the Collaborative Design Sessions, smaller workgroups will be formed to resolve issues identified in the Sessions. These workgroups will include the relevant stakeholders that participated in the original Collaborative Design Sessions, and additional stakeholders that are identified after the Collaborative Design Sessions. Over the subsequent few months, the workgroups will engage in issue resolution through interactive communication with their colleagues. As issues are resolved, they will be reviewed in by other workgroups to ensure relevance and completeness. The output from the workgroups will form the basis for the deliverables of this project.

C. What this Means for You

The standards and guidelines developed in this project will serve in the planning for delivery of care during an emergency surge environment where normal standards of care are diminished or non-existent. CDHS plans to disseminate the deliverables to local health departments, communities, healthcare facilities, individual licensed healthcare professionals, healthcare insurers and other key stakeholders for their use in planning for surge capacity.

Upon completion of this project, stakeholders will have access to:

- Standards and Guidelines Manual that will serve as a reference manual on existing statutory and regulatory requirements identifying what will be flexed or modified under different emergencies.
- Operational Tools that include forms, checklists and templates to facilitate and guide the adoption and implementation of statutory and regulatory requirements outlined in the Standards and Guidelines Manual.
- Training Curriculum outlining intended audience, means of delivery and frequency of training that will enable adherence to the policies and overall readiness of the healthcare delivery system.

D. Your Role as a Stakeholder

The best outcome of this project will only be accomplished with your help. From the outset, we envisioned that participation from a broad group of California healthcare stakeholders would be necessary to satisfactorily address the issues and impediments to planning for the optimal surge response. As a stakeholder, you have the opportunity to shape the issues and help to set the priority for their resolution.

Stakeholder organizations should identify personnel with the relevant experience to participate on this groundbreaking work, match relevant skills with initiatives. For example, on the Surge Planning initiative, participants who have responsibilities to moving patients and directly providing care would be appropriate. Likewise, risk managers, quality officers, and lawyers would be appropriate for the Standard and Liabilities initiative, and finally, reimbursement experts from payors and provider industries for Reimbursement.

The first Collaborative Design Session, focused on the operational aspects of surge planning – beds, facilities, labor, supplies, and equipment – will be a three-day session held from February 27 to March 1, 2007 in San Jose. The second Collaborative Design Session, focused on standards, guidelines and liability, will be a two-day session held on March 5 and 6, 2007 in Los Angeles. The third Collaborative Design Session, focused on reimbursement, will be a two-day session held on March 8 and 9, 2007 in Los Angeles.

A block of rooms has been set aside, at the rate indicated below, for each Collaborative Design Session, beginning the night before each session convenes. When making reservations please request the rate for the State of California Collaborative Design Session. Specific locations for the sessions are:

Surge Planning – February 27 – March 1, 2007
Holiday Inn San Jose
1740 North First St.
San Jose, CA 95112
(408) 793-3300
Room Rate: $115.00

D. Your Role as a Stakeholder (Continued)

Standards, Guidelines, and Liability – March 5 – 6, 2007
Westin Bonaventure
404 South Figueroa St.
Los Angeles, CA 90071
(213) 624-1000
Room Rate: $110.00

Reimbursement – March 8 – 9, 2007
Westin Bonaventure
404 South Figueroa St.
Los Angeles, CA 90071
(213) 624-1000
Room Rate: $110.00

We anticipate approximately 100 participants for each Collaborative Design Session. If the response for Collaborative Design Session participation is greater, we will implement a process of selection to determine the final attendees to the sessions. All interested stakeholders will be able to participate in the workgroups formed to resolve those issues and gaps identified in the Collaborative Design Sessions.

E. Getting Involved

Our goal is to create as many forums as possible for stakeholder participation. Thus, based on your availability and interest, you can participate in Collaborative Design Sessions, workgroups, or simply stay connected and informed via the following three channels:

- Internet: Stakeholder Web Portal, a website, will serve as the main communication vehicle and will allow you to (i) Obtain up-to-date project information and meeting schedules; (ii) Submit questions, ideas, and materials; (iii) Obtain copies of work documents; and (iv) Sign up for activities and email distribution lists. The portal can be accessed through the following URL: **http://www.dhs.ca.gov/epo/surge**

- Email: Stakeholders with questions, comments and concerns can send emails to **hcsurge@us.pwc.com**

- Phone: Stakeholders can call (213) 217-3900 to speak with a member of the project team. Stakeholders will be able to leave messages (accompanied with their name and phone number). A project team member will get back to the stakeholder as soon as possible.

We actively encourage you to get involved immediately. You can indicate your interest in participating in one or more of the Collaborative Design Session, resolving issues in workgroups, or being informed of progress throughout the project, by registering on our website or by calling PwC at (213) 217-3900. All registration will occur through the process outlined above.

On February 5 and February 8, 2007 we will be holding one-hour teleconference sessions at 11 am to provide an overview of the project. The teleconference dial-in number for February 5 is (888) 801-1508, the access code is 861511. The dial-in number for February 8 is (888) 801-1513, the access code is 861512.

Agenda Item 6

State of California **Department of Consumer Affairs**

Memorandum

To: **Licensing Committee** **Date: March 1, 2007**

From: **Board of Pharmacy**

Subject: **Legislative Proposals**

Staff is recommending approval of two additional omnibus provisions. Staff is recommending the proposals be included with the other 2007 omnibus provisions previously approved by the board.

Copies of the exact language are attached for consideration.

(1) Sections 4200 – 4200.3

Change the name of the CPJE from Multi-State Pharmacy Jurisprudence Examination for California to California Pharmacist – Patient Communication and Jurisprudence Exam. This change is recommended to ensure the name more accurately reflects the breadth of the exam.

(2) Section 4052 (a) (9)

Change the language in 4052 (a)(9) to also allow a pharmacist to provide an immunization pursuant to the National Protocol for Vaccinations in addition to the existing authority for a pharmacist to provide an immunization pursuant to a protocol with a prescriber.

The board will then need to develop a regulation with the specific protocol in it. This is similar to the process used for the state protocol for EC developed in conjunction with the Medical Board of California two years ago.

Dr. Jeff Goad, USC Professor, will attend this meeting and provide information about the CDC's immunization protocol.

Board of Pharmacy
2007 Omnibus Bill Proposed Language

Amend Sections 4200 – 4200.2 to read:

4200. Pharmacist License Requirements: Age; Education; Experience; Examination; Proof of Qualifications; Fees
(a) The board may license as a pharmacist any applicant who meets all the following requirements:
(1) Is at least 18 years of age.
(2)(A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or
(B) If the applicant graduated from a foreign pharmacy school, the foreign-educated applicant has been certified by the Foreign Pharmacy Graduate Examination Committee.
(3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.
(4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.
(5) Has completed 1,500 hours of pharmacy practice experience or the equivalent in accordance with Section 4209.
(6) Has passed a written and practical examination given by the board prior to December 31, 2003, or has passed the North American Pharmacist Licensure Examination and the ~~Multi-State Pharmacy Jurisprudence Examination for California~~ California Pharmacist – Patient Communication and Jurisprudence Examination on or after January 1, 2004.
(b) Proof of the qualifications of an applicant for licensure as a pharmacist, shall be made to the satisfaction of the board and shall be substantiated by affidavits or other evidence as may be required by the board.
(c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board, the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.
(Amended Stats. 2004, Chapter 695)

4200.1. Retaking Examinations; Limits; Requirements [Repeals 1-1-2010]
(a) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination four times, and may take the ~~Multi-State Pharmacy Jurisprudence Examination for California~~ California Pharmacist – Patient Communication and Jurisprudence Examination four times.
(b) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination and the ~~Multi-State Pharmacy Jurisprudence Examination for California~~ California Pharmacist – Patient Communication and Jurisprudence Examination four additional times each if he or she successfully

completes, at minimum, 16 additional semester units of education in pharmacy as approved by the board.
(c) The applicant shall comply with the requirements of Section 4200 for each application for reexamination made pursuant to subdivision (b).
(d) An applicant may use the same coursework to satisfy the additional educational requirement for each examination under subdivision (b), if the coursework was completed within 12 months of the date of his or her application for reexamination.
(e) For purposes of this section, the board shall treat each failing score on the pharmacist licensure examination administered by the board prior to January 1, 2004, as a failing score on both the North American Pharmacist Licensure Examination and the ~~Multi-State Pharmacy Jurisprudence Examination for California~~ California Pharmacist – Patient Communication and Jurisprudence Examination.
(f) From January 1, 2004, to July 1, ***2008, inclusive, the board shall collect data on the applicants who are admitted to, and take, the licensure examinations required by Section 4200. The board shall report to the Joint Committee on Boards, Commissions, and Consumer Protection before September 1, ***2008, regarding the impact on those applicants of the examination limitations imposed by this section. The report shall include, but not be limited to, the following information:
(1) The number of applicants taking the examination and the number who fail the examination for the fourth time.
(2) The number of applicants who, after failing the examination for the fourth time, complete a pharmacy studies program in California or another state to satisfy the requirements of this section and who apply to take the licensure examination required by Section 4200.
(3) To the extent possible, the school from which the applicant graduated and the school's location and the pass/fail rates on the examination for each school.
(g) This section shall remain in effect only until January 1, ***2010, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ***2010, deletes or extends that date.
(Amended Stats. 2006, Chapter 658)

4200.2. ~~Multi-State Pharmacy Jurisprudence Examination for California~~ California Pharmacist – Patient Communication and Jurisprudence Examination; Required Inclusions

When developing the ~~Multi-State Pharmacy Jurisprudence Examination for California~~ California Pharmacist – Patient Communication and Jurisprudence Examination, the board shall include all of the following:
(a) Examination items to demonstrate the candidate's proficiency in patient communication skills.
(b) Aspects of contemporary standards of practice for pharmacists in California, including, but not limited to, the provision of pharmacist care and the application of clinical knowledge to typical pharmacy practice situations that are not evaluated by the North American Pharmacy Licensure Examination.
(Added Stats. 2003, Chapter 539)

Amend Section 4052 to read:

4052. Furnishing to Prescriber; Permissible Procedures by Pharmacist in Health Care Facility or Clinic or for Other Health Care Provider

(a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.

(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) Furnish emergency contraception drug therapy as authorized by Section 4052.3.

(9) Administer immunizations pursuant to a protocol with a prescriber or pursuant to the Center for Disease Control's National Protocol for Vaccinations.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

(Amended Stats. 2006, Chapter 777)

Agenda Item 7

State of California Department of Consumer Affairs

Memorandum

To: **Licensing Committee** **Date: March 1, 2007**

From: **Board of Pharmacy**

Subject: **CE for Taking the Certification Examination for Geriatric Pharmacy**

Update: At the last Licensing Committee Meeting, the committee briefly reviewed the materials from the Commission for Certification for Geriatric Pharmacy (CCGP), which offers a program for pharmacists to become Certified Geriatric Pharmacists. The commission requested that the board grant CE for pharmacists who become certified. Four states are now awarding CE for becoming certified. However, the Licensing Committee did not take action on this item because no one from the commission appeared at the meeting.

The executive director of the commission (which is located in Virginia) cannot attend this Licensing Committee meeting, but is planning to attend the April Board Meeting to make a presentation on this examination directly to the board. Thereafter, the board can determine whether it wishes to move forward on the proposal or refer the matter back to the committee.

Below and on the following pages is the information about this examination provided to the committee at the December meeting.

Background:

Pharmacists are required to earn 30 hours of approved CE every two years as a condition of license renewal. Currently pharmacists can earn CE:

- Offered by approved providers (ACPE and the Pharmacy Foundation of California – 16 CCR 1732.05).
- Approved by Medical Board, Board of Podiatric Medicine, Board of Registered Nursing or Dental Board, if relevant to pharmacy practice (16 CCR 1732.2), or
- By petition of an individual pharmacist for a course that meets board standards for CE for pharmacists (16 CCR 1732.2).

Additionally, the board will award CE for:

- Attending one board meeting annually (6 hours of CE)
- Attending two committee meetings annually (2 hours of CE for each meeting, must be different committee meetings)
- Completing the PSAM, which is administered by the National Association of Boards of Pharmacy (6 units)

Proposal:

The Commission for Certification in Geriatric Pharmacy (CCGP) offers a program for pharmacists to become Certified Geriatric Pharmacists. There are currently 1,300 certified geriatric pharmacists in the United States, Canada, Australia and other

countries.

To become certified, the individual must pass a 3-hour, 150-question examination covering three major areas: Patient Specific, Disease Specific and Population Specific activities. The exam has been psychometrically validated by a firm specializing in such processes.

Two states, Ohio and Washington, recognize CCGP's certification examination for continuing education credits. Recently the board was notified about this examination and was asked to consider its appropriateness for continuing education (CE) credit.

I have provided background material about the CCGP certification examination in this tab section.

Q: Does the committee wish to recommend CE for proof of completing/passing the CCGP exam?

Comment:

The board's legal counsel now advises that the board needs to adopt a regulation to authorize the award of CE for board meetings, committee meetings and the PSAM. Accordingly, such a regulation will be brought to a future Legislation and Regulation Committee.

If Licensing Committee recommends, and the board agrees, to award CE for the CCGP exam, staff will add a provision to the proposed regulation.

September 5, 2006

Patricia F. Harris
California Board of Pharmacy
1625 N Market Boulevard, N219
Sacramento, CA 95834

Dear Ms. Harris:

I am writing to request that the California Board of Pharmacy consider recognition of our certification examination as at least one approved source for purposes of meeting the Pharmacy Board's current Continuing Education requirements.

At present, at least two states, Ohio and Washington, recognize CCGP's certification examination for continuing education credits. We are seeking similar recognition among the other state boards of pharmacy.

Our examination is 3 hours and is composed of 150 multiple choice questions addressing three major domains: Patient Specific, Disease Specific, and Population Specific activities. It has been structured according to currently excepted psychometric principles and is administered on our behalf by Applied Measurement Professionals (AMP), one of the major psychometric firms in the United States. The exam, itself, is based upon a detailed content outline that was produced from a Practice Analysis in 2003. I have enclosed a copy of our current Candidate Handbook. It provides an outline of that Content Map. The Candidate Handbook also provides a brief description of CCGP and sets forth the rules and policies for earning and maintaining certification.

Our certification is the only population specific specialty designation in the pharmacy profession and has been awarded to more than 1,300 board Certified Geriatric Pharmacists, in good standing who practice in the United States, Canada, Australia and other international locations. We believe that CCGP certification is tangible evidence that a board Certified Geriatric Pharmacist is uniquely qualified to provide pharmacy care to the frail and elderly. Furthermore, while the new Medicare Part D program is still in its infancy, we are beginning to see evidence that CCGP certification is becoming at least one criterion for selecting pharmacists for participation on Pharmacy and Therapeutics Committees and networks of providers used by Pharmacy Benefit Managers and Prescription Drug Plans to provide drug benefit services.

We would appreciate the Board's willingness to consider our request. Please feel free to visit our website www.ccgp.org for more information, including the ability to download our Candidate Handbook. If you have any questions, you can contact me by email at lhoxie@ccgp.org or by telephone at (703) 535-3038.

Sincerely,

Lance O. Hoxie
Executive Director

COMMISSION FOR CERTIFICATION
IN GERIATRIC PHARMACY

1321 Duke Street • Alexandria, VA 22314
703.535.3038 • Fax 703.739.1500
www.ccgp.org • info@ccgp.org

Certification Examination in Geriatric Pharmacy

Sponsored by:
Commission for Certification in Geriatric Pharmacy (CCGP)

January 2006

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All questions and requests for information about CCGP Certification should be directed to:

CCGP
1321 Duke Street
Alexandria, VA 22314-3563
703/535-3036
FAX 703/739-1500

All questions and requests for information about examination scheduling should be directed to:

Applied Measurement Professionals, Inc.
8310 Nieman Road
Lenexa, KS 66214
Voice: 913/541-0400
Fax: 913/541-0156
Website: www.goAMP.com

ABOUT CCGP

The Commission for Certification in Geriatric Pharmacy (CCGP) is a nonprofit corporation created in February 1997 by the American Society of Consultant Pharmacists (ASCP) Board of Directors. CCGP was created to oversee the certification program in geriatric pharmacy by establishing eligibility criteria and other program policies.

The CCGP Board of Commissioners is comprised of seven elected pharmacists; three appointed commissioners (consumer, and payor representative, and a physician with experience and/or credentialing in geriatric practice); one representative appointed by the American Society of Consultant Pharmacists (ASCP) Board of Directors, the ASCP Executive Director, and the CCGP Executive Director (ex officio). The membership of CCGP is comprised of individuals who have passed the Certification Examination in Geriatric Pharmacy and are credentialed.

ABOUT THIS HANDBOOK

This Candidate Handbook is only a guide. The information, procedures and fees detailed in this publication may be amended, revised or otherwise altered at any time and without advance notice by CCGP. The provision of this handbook does not confer any rights upon the applicant. For the most current version of this handbook, please visit www.ccgp.org or www.goAMP.com.

STATEMENT OF NONDISCRIMINATION POLICY

CCGP does not discriminate among applicants on the basis of age, gender, race, religion, national origin, disability, sexual orientation or marital status.

CERTIFICATION

The certification program in geriatric pharmacy is intended to recognize those pharmacists who demonstrate knowledge of geriatric pharmacotherapy and the knowledge and skills required to provide pharmaceutical care to the elderly. These pharmacists may practice in a variety of settings, including hospital, community or long-term care.

TESTING AGENCY

Applied Measurement Professionals, Inc. (AMP) is the professional testing agency contracted by CCGP to assist in the development, administration, scoring and analysis of the certification examination. AMP services also include the reporting of scores to candidates who take the examination. AMP is a research and development firm that conducts professional competency assessment research and provides examination services for a number of credentialing programs.

EXAMINATION POLICIES

CCGP offers the *Certification Examination in Geriatric Pharmacy* to individuals in geriatric pharmacy practice. The examination consists of 150 multiple-choice questions. Candidates will be allowed three hours to complete the examination. Individuals passing the Certification Examination in Geriatric Pharmacy are credentialed as Certified Geriatric Pharmacists (CGP).

CCGP with the advice and assistance of AMP prepares the examinations. Individuals with expertise in geriatric pharmacy practice write the questions and review them for relevancy, consistency, accuracy and appropriateness.

ELIGIBILITY REQUIREMENTS

To be eligible for the Certification Examination in Geriatric Pharmacy, an applicant must currently be a licensed pharmacist and must have a minimum of two years of experience as a licensed pharmacist. Applications must be accompanied by:

1) a photocopy of current state pharmacy registration certificate/license, and
2) a check, money order or credit card payment.

AUDIT PROCEDURE

CCGP reserves the right to audit any application submitted for the Certification Examination in Geriatric Pharmacy.

FOREIGN TRAINED/FOREIGN LICENSED APPLICANTS

Pharmacists who are not licensed to practice pharmacy in the United States may apply to take the Certification Examination in Geriatric Pharmacy. However, the practice analysis upon which the examination is based was conducted in the United States and CCGP does not claim that these processes or certification are accepted or recognized outside of the United States. Applicants who are not licensed to practice pharmacy in the United States must provide notarized documentation of their legal authorization to practice pharmacy in another country.

APPLICATION FEE

The Application Fee for the examination is $600. Fees may be paid by check or money order (made payable to CCGP), or by credit card (VISA, MasterCard, Discover or American Express). DO NOT SUBMIT CASH.

Candidates must submit the appropriate fee with the application form.

Returned checks and/or declined credit card transactions will be subject to a $25 handling fee. You must send a certified check or money order for the amount due, including the NSF fee, to CCGP to cover returned check and/or declined credit card transactions.

EXAMINATION ADMINISTRATION

The examination is delivered by computer at over 150 AMP Assessment Centers geographically located throughout the United States, Canada and Australia. Generally, there are no application deadlines and a candidate may submit an Application and Application Fee at any time. Testing is normally the first full week of each month. The examination is administered by appointment only Monday through Friday at 9:00 a.m. and 1:30 p.m. Available dates will be indicated when scheduling your examination. Candidates are scheduled on a first-come, first-served basis.

HOLIDAYS

The examinations are not offered on the following holidays:

New Year's Day
Martin Luther King Day
Presidents' Day
Good Friday
Memorial Day
Independence Day (July 4)
Labor Day
Columbus Day
Veterans' Day
Thanksgiving Day (and the following Friday)
Christmas Eve Day
Christmas Day
New Year's Eve Day

REGISTERING FOR AN EXAMINATION

Candidates should ensure that the CCGP Application has been properly completed and that the information provided is accurate. Your careful attention will enable prompt and efficient processing. Candidates will not be able to schedule an examination appointment with AMP until the Application has been processed. AMP will send written notification to registered candidates with examination scheduling procedures.

SCHEDULING AN EXAMINATION

After the candidate has received written confirmation from CCGP, there are two ways to schedule an appointment for the examination.

1. Schedule Online: The candidate may schedule an examination appointment online at any time by using AMP's online application/scheduling service. To use this service, follow these easy steps:
   - Go to www.goAMP.com and select "Candidates."
   - Follow the simple, step-by-step instructions to select your examination program and schedule an examination.

OR

2. Telephone Scheduling: Call AMP at 888/519-9901 to schedule an examination appointment. This toll-free number answered from 7:00 a.m. to 7:00 p.m. (Central Time) Monday through Thursday, 7:00 a.m. to 5:00 p.m. on Friday and 8:30 a.m. to 5:00 on Saturday.

When scheduling an examination, be prepared to confirm a location, a preferred date and time for testing, and to provide your Social Security number as a unique identification number. AMP will use your Social Security number only as an identification number in maintaining your record. When you contact AMP to schedule an examination appointment, you will be notified of the time to report to the Assessment Center. Please make a note of it because you will NOT receive an admission letter.

If you call AMP by 3:00 p.m. Central Time on...	Depending on availability, your examination may be scheduled beginning...
Monday	Thursday
Tuesday	Friday
Wednesday	Monday
Thursday	Tuesday
Friday	Wednesday

ASSESSMENT CENTER LOCATIONS

AMP Assessment Centers have been selected to provic accessibility to the most candidates in all states and major metropolitan areas. AMP Assessment Centers are typically located in H&R Block offices. International locations are also offered in Canada and Australia. A current listing of AMP Assessment Centers, including addresses and driving directions, may be viewed at AMP's website located at www.goAMP.com. Specific address information will be provided when a candidate schedules an examination appointment.

SPECIAL ARRANGEMENTS FOR CANDIDATES WITH DISABILITIES

CCGP and AMP comply with the Americans with Disabilities Act and strive to ensure that no individual with a disability is deprived of the opportunity to take the examination solely by reason of that disability. CCGP and AMP will provide reasonable accommodations for candidates with disabilities.

Wheelchair access is available at all Assessment Centers. Candidates with visual, sensory or physical disabilities that would prevent them from taking the examination under standard conditions may request special accommodations and arrangements. Candidates testing with approved special accommodations should schedule their test via AMP's toll-free number to ensure their accommodations are confirmed. Be sure to inform CCGP and AMP of your need for special accommodations when ca' ing to schedule your examination.

TELECOMMUNICATION DEVICES FOR THE DEAF

AMP is equipped with Telecommunication Devices for the Deaf (TDD) to assist deaf and hearing-impaired candidates. TDD calling is available 8:30 a.m. to 5:00 p.m. (Central Time) Monday-Friday at 913/495-4437. This TDD phone option is for individuals equipped with compatible TDD machinery.

EXAMINATION APPOINTMENT CHANGES

A candidate may reschedule an examination appointment at no charge **once** by calling AMP at 888/519-9901 at least four business days prior to the scheduled testing session. (See table below.)

If the examination is scheduled on...	AMP must be contacted by 3:00 p.m. Central Time to reschedule the examination by the previous...
Monday	Tuesday
Tuesday	Wednesday
Wednesday	Thursday
Thursday	Friday
Friday	Monday

MISSED APPOINTMENTS AND CANCELLATION

A candidate will forfeit the examination registration and all fees paid to take the examination under the following circumstances.

- The candidate wishes to reschedule an examination but fails to contact AMP at least four business days prior to the scheduled testing session,
- The candidate wishes to reschedule a second time,
- The candidate appears more than 15 minutes late for an examination, or
- The candidate fails to report for an examination appointment.

A complete Application and appropriate fee are required to re-register for the examination.

INCLEMENT WEATHER, POWER FAILURE OR EMERGENCY

In the event of inclement weather or unforeseen emergencies on the day of an examination, AMP will determine whether circumstances warrant the cancellation, and subsequent rescheduling, of an examination. The examination will usually not be rescheduled if the Assessment Center personnel are able to open the Assessment Center. If power to an Assessment Center is temporarily interrupted during an administration, your examination will restart where you left off and you may continue the examination.

Candidates may contact AMP's Weather Hotline at 913/495-4418 (24 hours/day) prior to the examination to determine if AMP has been advised that any Assessment Centers are closed. Every attempt is made to administer the examination as scheduled; however, should an examination be canceled at an Assessment Center, all scheduled candidates will receive notification following the examination regarding rescheduling or reapplication procedures.

PREPARING FOR THE EXAMINATION

Your primary objective in preparing for the examination is to pass. Other objectives such as learning new material and reviewing old material are critical toward this objective. Begin your study by developing your strategy for success.

A good study strategy includes preparation. To prepare, determine first what you need to learn, choose your study materials, and select a quiet, comfortable place that allows you to focus. Before you begin, check to make sure you have everything you need. Try to avoid interruptions for any reason.

Developing a study plan will allow you to learn the most as you study. Include setting goals in your study plan. Review what you have studied as often as possible. The more you review, the more you will retain.

Candidates may also wish to purchase CCGP's Self-Assessment Examination (SAE). The SAE is designed to help pharmacists measure their knowledge and skills in geriatric pharmacy practice. It will help identify those areas where additional continuing education may be helpful. It will also provide a candidate with a simulated experience in undertaking the actual certification examination. Once areas of additional continuing education would be helpful, candidates may wish to take advantage of a variety of resources such as www.geriatriacpharmacyreview.com to supplement existing knowledge. Please see page 13 for more information concerning the SAE.

TAKING THE EXAMINATION

Your examination will be given by computer at an AMP Assessment Center. You do not need any computer experience or typing skills to take your examination. On the day of your examination appointment, report to the Assessment Center no later than your scheduled testing time. Look for the signs indicating AMP Assessment Center Check-in. A CANDIDATE WHO ARRIVES MORE THAN 15 MINUTES AFTER THE SCHEDULED TESTING TIME WILL NOT BE ADMITTED.

IDENTIFICATION

To gain admission to the Assessment Center, you must present two forms of identification, one with a current photograph. Both forms of identification must be current and include the candidate's current name and signature. The candidate will be required to sign a roster for verification of identity.

Acceptable forms of photo identification include a current driver's license with photograph, a current state identification card with photograph, a current passport, or a current military identification card with photograph. Employment ID cards, student ID cards and any type of temporary identification are NOT acceptable as the primary form of identification.

You must have proper identification to gain admission to the Assessment Center. Failure to provide appropriate identification at the time of the examination is considered a missed appointment. There will be no refund of your examination fee.

SECURITY

CCGP and AMP maintain examination administration and security standards that are designed to assure that all candidates are provided the same opportunity to demonstrate their abilities. The Assessment Center is continuously monitored by audio and video surveillance equipment for security purposes.

The following security procedures apply during the examination:

- Examinations are proprietary. No cameras, notes, tape recorders, Personal Digital Assistants (PDAs), pagers or cellular phones are allowed in the testing room.
- Hand-held, silent, non-printing, battery-operated calculators may be used. Candidates may NOT use calculators which have either word processing or word storage capabilities (complete A-Z keypad). All calculators will be examined by the proctor before a candidate is admitted to the examination area. Candidates are responsible for providing their own calculators. Candidates cannot share calculators during the examination.
- No guests, visitors or family members are allowed in the testing room or reception areas.
- No personal items, valuables, or weapons should be brought to the Assessment Center. Only keys and wallets may be taken into the testing room and AMP is not responsible for items left in the reception area.

EXAMINATION RESTRICTIONS

- No personal belongings will be allowed in the Assessment Center. Pencils will be provided during check-in.
- You will be provided with scratch paper to use during the examination. You must return the scratch paper to the supervisor at the completion of testing, or you will not receive a score report. No documents or notes of any kind may be removed from the examination room.
- No questions concerning the content of the examination may be asked during the examination.
- Eating, drinking or smoking will not be permitted in the Assessment Center.
- You may take a break whenever you wish, but you will not be allowed additional time to make up for time lost during breaks.

MISCONDUCT

Individuals who engage in any of the following conduct may be dismissed from the examination, their scores will not be reported and examination fees will not be refunded. Examples of misconduct are when a candidate:

- creates a disturbance, is abusive, or otherwise uncooperative;
- displays and/or uses electronic communications equipment such as pagers, cellular phones, PDAs;
- gives or receives help or is suspected of doing so;
- attempts to record examination questions or make notes;
- attempts to take the examination for someone else; or
- is observed with notes, books or other aids.

COPYRIGHTED EXAMINATION QUESTIONS

All examination questions are the copyrighted property of CCGP. It is forbidden under federal copyright law to copy, reproduce, record, distribute or display these examination questions by any means, in whole or in part. Doing so may subject you to severe civil and criminal penalties.

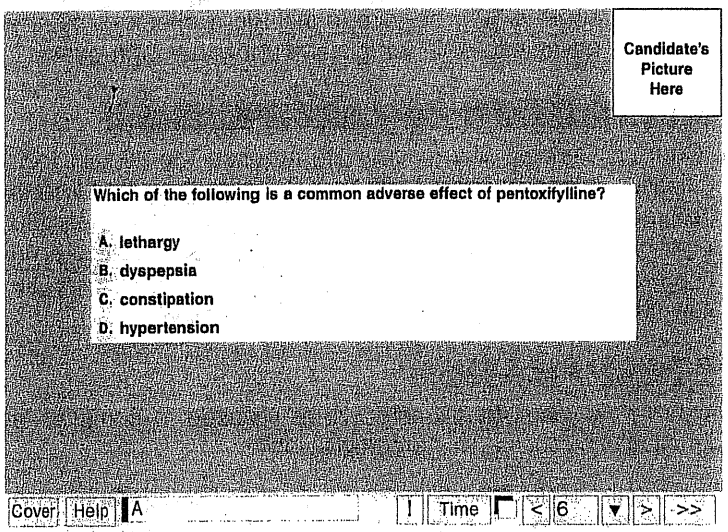
PRACTICE EXAMINATION

After your identification has been confirmed, you will be directed to a testing carrel. You will be instructed on-screen to enter your Social Security number. You will take your photograph which will remain on screen throughout your examination session. This photograph will also print on your score report.

Prior to attempting the examination, you will be given the opportunity to practice taking an examination on the computer. The time you use for this practice examination is NOT counted as part of your examination time or score. When you are comfortable with the computer testing process, you may quit the practice session and begin the timed examination.

TIMED EXAMINATION

Following the practice examination, you will begin the timed examination. Before beginning, instructions for taking the examination are provided on-screen.



The computer monitors the time you spend on the examination. The examination will terminate if you exceed the time allowed. You may click on the "Time" box in the lower right-hand corner of the screen or select the Time key to monitor your time. A digital clock indicates the time remaining for you to complete the examination. The Time feature may be turned off during the examination.

Only one examination question is presented at a time. The question number appears in the lower right hand corner of the screen. Choices of answers to the examination question are identified as A, B, C, or D. You must indicate your choice by either typing in the letter in the response box in the lower left hand of the computer screen or clicking in the option using the mouse. To change your answer, enter a different option by pressing the A, B, C, or D key or by clicking on the option using the mouse. You may change your answer as many times as you wish during the examination time limit.

To move to the next question, click on the forward arrow (>) in the lower right portion of the screen or select the NEXT key. This action will move you forward through the examination question by question. If you wish to review any question or questions, click the backward arrow (<) or use the left arrow key to move backward through the examination.

An examination question may be left unanswered for return later in the examination session. Questions may also be bookmarked for later review by clicking in the blank square to the right of the Time button. Click on the hand icon or select the NEXT key to advance to the next unanswered or bookmarked question on the examination. To identify all unanswered and bookmarked questions, repeatedly click on the hand icon or press the NEXT key. When the examination is completed, the number of examination questions answered is reported. If not all questions have been answered and there is time remaining, return to the examination and answer those questions. Be sure to provide an answer for each examination question before ending the examination. There is no penalty for guessing.

CANDIDATE COMMENTS

During the examination, online comments may be provided for any question by clicking on the button displaying an exclamation point (!) to the left of the Time button. This opens a dialogue box where comments may be entered. Comments will be reviewed, but individual responses will not be provided.

FOLLOWING THE EXAMINATION

After completing the examination, candidates are asked to complete a short evaluation of their examination experience. Then, candidates are instructed to report to the examination proctor to receive their score report. Scores are reported in written form only, in person or by U.S. mail. Scores are not reported over the telephone, by electronic mail or by facsimile.

Your score report will indicate a "pass" or "fail." Your pass/fail status is determined by your raw score. Additional detail is provided in the form of raw scores by major content category. A raw score is the number of questions you answered correctly.

PASS/FAIL SCORE DETERMINATION

Examination scores are reported as raw scores and scaled scores. A raw score is the number of correctly answered questions; a scaled score is statistically derived from the raw score. Your total score determines whether you pass or fail; it is reported as a scaled score ranging between 0 and 99.

The minimum scaled score needed to pass the examination has been set at 75 scaled score units. The reason for reporting scaled scores is that different forms (or versions) of the examination may vary in difficulty. As new forms of the examination are introduced each year, a certain number of questions in each content area are replaced. These changes may cause one form of the examination to be slightly easier or harder than another form. To adjust for these differences in difficulty, a procedure called "equating" is used. The goal of equating is to ensure fairness to all candidates.

In the equating process, the minimum raw score (number of correctly answered questions) required to equal the scaled passing score of 75 is statistically adjusted (or equated). For instance, if the examination is determined to be more difficult than the previous form of the examination, then the minimum raw passing score required to pass will be slightly lower than the original raw passing score. If the examination is easier than the previous form of the examination, then the minimum raw score will be higher. Equating helps to assure that the scaled passing score of 75 represents the same level of competence no matter which form of the examination a candidate takes.

In addition to the candidate's total scaled score and scaled score required to pass, raw scores (the actual number of questions answered correctly) are reported for the major categories on the content outline. The number of questions answered correctly in each major category is compared to the total number of questions possible in that category on the score report (e.g., 15/20). Content categorical information is provided to assist candidates in identifying areas of relative strength and weakness; however, passing or failing the examination is based only on the candidate's total scaled score.

SCORES CANCELLED BY CCGP OR AMP

CCGP and AMP are responsible for the validity and integrity of the scores they report. On occasion, occurrences, such as computer malfunction or misconduct by a candidate, may cause a score to be suspect. CCGP and AMP reserve the right to void or withhold examination results if, upon investigation, violation of its regulations is discovered.

IF YOU PASS THE EXAMINATION

If you pass the examination, CCGP will request that you sign a Declaration on the Appropriate use of the Credential and remit a five-year certification fee. Following receipt of the Declaration and fee, CCGP will send a Certificate, in your name, officially designating you as a Certified Geriatric Pharmacist.

IF YOU DO NOT PASS THE EXAMINATION

There is no limit to the number of times candidates may attempt the examination. If you were unsuccessful in your examination attempt, you may reregister once every 90 days by completing another Application and submitting appropriate fees. The fee to retake the examination after an unsuccessful attempt is $300, if the examination is retaken within two years. After two years, the full fee ($600) must be paid.

FAILING TO REPORT FOR AN EXAMINATION

A candidate who fails to report for an examination forfeits all fees paid to take the examination. A completed application and examination fee are required to reapply for examination.

CONFIDENTIALITY

Information about candidates for testing and their examination results are considered confidential. Individual examination scores are released ONLY to the individual candidate. Questions concerning examination results should be referred to the CCGP Candidate Services Department in writing.

RECOGNITION OF CERTIFICATION

Candidates who pass the certification examination are entitled to use the designation "CGP" for Certified Geriatric Pharmacist. CCGP will provide certificants with a certificate of recognition suitable for framing. In addition, certificants will be entitled to additional items, such as lapel pins, that display the logo for Certified Geriatric Pharmacist. Contact CCGP for additional information.

QUESTIONS ABOUT THE EXAMINATION

Candidates may not have access to the examinations or to specific questions except during administration of the examination. Candidates may comment on any question, the administration of the examination or the test center facilities on their answer sheet on the day of the examination. Individual responses to question comments will not be provided.

DUPLICATE SCORE REPORTS

Requests for duplicate score reports must be made in writing t AMP within one year of the examination date. Your request must include your name, social security number, mailing address, examination date, test center and signature. The fee for a duplicate score report is $25; be sure to include a check or money order made payable to AMP for this amount with your request.

CONTINUATION OF CERTIFICATION

All Certified Geriatric Pharmacists are required to maintain their certification, in good standing with the CCGP. To do so, certificants will be requested to submit an annual questionnaire and a signed Attestation of a Valid License. Failure to submit a signed Attestation may jeopardize the certificant's good standing with CCGP, ultimately resulting in suspension of their certified standing.

RECERTIFICATION

Every five (5) years, certificants will be required to complete a recertification process. This process involves:

1) paying the $600 Recertification Application Fee and achieving a passing score on a multiple-choice objective examination, based on the content outline of the Certification Examination in Geriatric Pharmacy

OR

2) paying the $600 Recertification Application Fee and successfully completing the Professional Development Program fo CGP Recertification. Please visit the CCGP website for furthe information on this program at www.ccgp.org. Recertification is required to provide assurance that practitioners are maintaining their knowledge and skills in geriatric pharmacy practice.

RECERTIFICATION GRACE PERIOD

If a CCGP Certified Geriatric Pharmacist (CGP) fails to successfully complete the recertification process, extension of her/his certification may be granted for six months while he/she seeks to successfully complete the process. If a CCGP certified pharmacist does not complete the process within that period, then the individual's status as a CGP will lapse. Once certification has lapsed, reinstatement can be achieved only by successfully completing the entire certification process.

EXAMINATION CONTENT

To begin your preparation in an informed and organized manner, you should know what to expect from the actual examination in terms of the content. Information regarding the content of the examination is presented in this handbook. The content outline will give you a general impression of the examination and, with closer inspection, can give you specific study direction by revealing the relative importance given to each category on the examination.

Note: Medications on the certification examination will be referred to by the generic name only (USAN or USP name). Medicatio which are known by the British Approved Name outside th United States will have this name in parentheses. For example: albuterol (salbutamol). Laboratory examination results will be presented in both conventional and international units. The content for the examination is based on a job analysis and is described in the following detailed content outline.

Certified Geriatric Pharmacist Detailed Content Outline

[1] Percentages for minor content area are approximate, and based on the number of items in that section.
[2] Shaded "X" denotes that NO items should be written at the indicated cognitive level for the task.

	QUESTIONS			
	Recall	Application	Analysis	TOTAL %
I. PATIENT SPECIFIC ACTIVITIES	**12**	**25**	**15**	**35%**
A. Collect and Evaluate Patient-Specific Information	**2**	**7**	**2**	**21%**
1. Interpret and apply knowledge of the following to the provision of pharmaceutical care for older adults:				
a. incidence of disease, comorbidity and disability			X[2]	
b. patterns of medication use			X	
c. causes of morbidity and mortality			X	
2. Assess and apply understanding of the following issues to the provision of pharmaceutical care for older adults:				
a. continuum of care			X	
b. wellness and health promotion			X	
c. loss of independence			X	
d. end of life issues (advance directives, treatment issues, quality of life choices)			X	
e. ethical issues				
3. Evaluate the social aspects of aging in the provision of pharmaceutical care for older adults related to the following:				
a. economic issues			X	
b. availability of community based services (referrals and triage)			X	
c. isolation			X	
d. losses			X	
e. role of caregiver				
4. Communicate with elderly patients, their caregivers and healthcare professionals:				
a. recognize communication barriers including age-related sensory and cognitive impairments, illiteracy, and language and cultural differences		X	X	
b. apply strategies to overcome communication barriers			X	
c. apply privacy and confidentiality principles			X	
d. ensure patient understanding of prescribed therapy				
5. Evaluate physiological changes that accompany aging (e.g., sensory, body composition, organ system function)			X	
6. Interpret and monitor laboratory results and procedures for the older patient				
7. Evaluate and apply results of standardized assessment tools (MMSE, GDS, etc.)				
8. Recognize and assess altered disease state presentations in the elderly			X	
9. Recognize and assess altered psychological status in the elderly			X	
10. Identify and assess compliance/adherence issues affecting potential treatment plans (e.g., memory loss, sensory changes, hearing, cognition, patient beliefs, economics, and learning disabilities)				
11. Obtain an accurate drug history including over the counter and alternative/complementary medications		X	X	
12. Obtain and/or evaluate relevant physical assessment information			X	
13. Apply principles of pharmacokinetic and pharmacodynamic changes associated with aging to the design of the pharmacotherapy regimen				
B. Identify, Resolve and Prevent Medication Therapy – Related Problems	**3**	**3**	**10**	**31%**
1. Untreated or under-treated conditions				
2. Improper drug selection				
3. Subtherapeutic or Supratherapeutic dosage				
4. Compliance/Adherence issues:				
a. monitor patient's compliance/adherence with medications and apply strategies to educate the patient and/or caregiver, and encourage compliance/adherence with therapy			X	
b. promote elder-appropriate drug labeling and packaging			X	

Certified Geriatric Pharmacist Detailed Content Outline [1] Percentages for minor content area are approximate, and based on the number of items in that section. [2] Shaded "X" denotes that NO items should be written at the indicated cognitive level for the task.	QUESTIONS			
	Recall	Application	Analysis	TOTAL %
5. Adverse drug events				
6. Drug interactions				
7. Drug use without indication				
8. Treatment failures				
C. Determine Patient's Pharmaceutical and Related Health Care Needs and Integrate into Care Plan	**0**	**1**	**2**	**6%**
D. Select Drug Therapy Goals which Focus on Function and Quality of Life	**1**	**2**	**X**	**6%**
E. Design and Implement a Therapeutic Regimen in Collaboration with the Patient and Other Health Care Professionals	**1**	**5**	**1**	**13%**
1. Apply concept of risk: benefit for each drug				
2. Recommend non-prescription drugs			X	
3. Educate patient on therapy options – generics, alternative therapies, nondrug therapies, formulary options, etc.			X	
4. Educate patient on medication-related problems (e.g., side effects of medication, drug interactions)			X	
5. Recognize need for referral to specialized healthcare provider for further evaluation/treatment			X	
F. Patient Monitoring Plan	**5**	**7**	**0**	**23%**
1. Design plan to monitor for safety, effectiveness and achievement of therapeutic goals			X	
2. Implement plan			X	
3. Evaluate its effects on quality of life issues				
4. Document steps and outcomes of pharmaceutical care plan		X	X	
II. DISEASE SPECIFIC ACTIVITIES	**20**	**43**	**17**	**53%**
A. Cardiovascular Disorders – e.g., Hypertension, Heart Failure, Ischemic Heart Disease, Myocardial Infarction, Cardiac Arrhythmias, Hyperlipidemia, Peripheral Vascular Disease	**2**	**5**	**2**	**11%**
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
B. Dermatologic Disorders – e.g., Pressure Ulcers, Drug Induced Skin Disorders, Xerosis, Fungal Rashes, Other Common Skin Disorders	**1**	**1**	**0**	**3%**
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
C. Endocrine and Exocrine Disorders – e.g., Thyroid Disorders, Diabetes Mellitus, SIADH, Disorders of the Adrenal Gland, Paget's Disease, Hormone Replacement Therapy	**2**	**4**	**2**	**10%**
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				

Certified Geriatric Pharmacist Detailed Content Outline

[1] Percentages for minor content area are approximate, and based on the number of items in that section.
[2] Shaded "X" denotes that NO items should be written at the indicated cognitive level for the task.

	QUESTIONS			
	Recall	Application	Analysis	TOTAL %
D. Gastrointestinal Disorders- e.g., Peptic Ulcer Disease, Gastro-Esophageal Reflux Disease, Diarrhea and Constipation, Irritable Bowel Syndrome, Inflammatory Bowel Disease, Hepatic Disorder (Cirrhosis), Pancreatitis, Cholelithiasis	**1**	**4**	**1**	**7%**
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
E. Hematologic Disorders – e.g., Anemias, Disorders of Hemostasis, Thrombocytopenia, Disorders of White Blood Cells	**1**	**2**	**1**	**5%**
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
F. Infectious Diseases – e.g., Pneumonia, Urinary Tract Infection, Tuberculosis, Herpes Zoster, AIDS, Skin and Soft Tissue Infections, Hepatitis, Bone and Joint Infections, Genitourinary Tract Infection, Influenza, Ophthalmic Infections, Nosocomial Infections, Drug Resistance, Immunizations	**2**	**3**	**2**	**9%**
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
G. Musculoskeletal Disorders – e.g., Osteoarthritis, Rheumatological Diseases, Osteoporosis, Gout, Acute and Chronic Pain, Foot Disorders	**2**	**4**	**2**	**10%**
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
H. Neurological Disorders – e.g., Cerebrovascular Disease (Stroke, Transient Ischemic Attacks), Movement Disorders (Parkinson's Disease, Essential Tremor), Dementias (Alzheimer's Disease, Lewy Body Disease, Ischemic Vascular Dementia), Delirium, Seizure Disorders, Neuropathies, Acute and Chronic Pain Syndromes	**2**	**5**	**2**	**11%**
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				

Certified Geriatric Pharmacist Detailed Content Outline

[1] Percentages for minor content area are approximate, and based on the number of items in that section.
[2] Shaded "X" denotes that NO items should be written at the indicated cognitive level for the task.

	QUESTIONS			
	Recall	Application	Analysis	TOTAL %
I. Nutrition and Hydration Disorders – e.g., Malnutrition, Dehydration, Fluid and Electrolyte Disorders	**1**	**2**	**1**	**5%**
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
J. Oncology – e.g., Breast Cancer, Skin Cancer, Prostate Cancer, Lung Cancer, Colorectal Cancer, Brain Tumors	**1**	**1**	**0**	**3%**
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
K. Ophthalmology – e.g., Glaucoma, Dry Eyes, Blepharitis, Macular Degeneration, Cataracts	**1**	**1**	**0**	**3%**
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
L. Psychiatric Disorders – e.g., Depression and Other Mood Disorders, Schizophrenia and Other Psychotic Disorders, Sleep Disturbances, Anxiety Disorders, Behavioral Disorders, Alcohol and Drug Abuse	**2**	**5**	**2**	**11%**
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
M. Genitourinary Disorders – e.g., Urinary Incontinence, Benign Prostatic Hyperplasia, Sexual Dysfunction, Renal Failure	**1**	**3**	**1**	**6%**
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
N. Respiratory Disorders – e.g., Chronic Obstructive Pulmonary Disease, Asthma	**1**	**3**	**1**	**6%**
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	

Certified Geriatric Pharmacist Detailed Content Outline [1] Percentages for minor content area are approximate, and based on the number of items in that section. [2] Shaded "X" denotes that NO items should be written at the indicated cognitive level for the task.	QUESTIONS			
	Recall	Application	Analysis	TOTAL %
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
III. POPULATION SPECIFIC ACTIVITIES	**5**	**5**	**8**	**12%**
A. Research	**1**	**1**	**4**	**33%**
1. Conduct drug use evaluations (DUE) and drug use review (DUR)			X	
2. Apply DUE/DUR results to improve the quality of care			X	
3. Evaluate and apply research pertinent to the elderly				
4. Interpret and apply geriatric practice guidelines				
B. Economics and Access	**1**	**1**	**3**	**28%**
1. Develop and implement formulary management/protocols				
2. Interpret pharmacoeconomic data			X	
3. Develop and implement practice guidelines				
4. Evaluate costs/benefits issues that influence access to medications or therapy for specific patients				
C. Health Policy	**3**	**3**	**1**	**39%**
1. Communicate with healthcare professionals to improve quality of care			X	
2. Ensure that privacy and confidentiality standards are maintained		X	X	
3. Optimize the Continuum of Care process				
TOTAL TEST	**37**	**73**	**40**	**100%**

SAMPLE QUESTIONS

1. Which of the following is a common adverse effect of pentoxifylline?

   A. lethargy
   B. dyspepsia
   C. constipation
   D. hypertension

2. Which of the following drugs is most likely to contribute to falls in an elderly patient?
   A. aspirin
   B. alenodronate
   C. prazosin HCl
   D. cefadroxil monohydrate

3. Which of the following should be included in the documentation of a pharmaceutical care plan?

   1. the decision-making process that has been used
   2. any interventions that have been made
   3. a description of patient-specific outcomes

   A. 1 and 2 only
   B. 1 and 3 only
   C. 2 and 3 only
   D. 1, 2, and 3

4. Which of the following is the recommended daily intake of elemental calcium for postmenopausal women, who are not taking hormone replacement therapy?
   A. 500 mg
   B. 1000 mg
   C. 1500 mg
   D. 2000 mg

5. An elderly man with diabetes mellitus presents with cellulitis of the lower right leg. The patient is started on cephalexin HCl 500 mg po q6h with no significant improvement after 5 days of treatment. Which of the following is the most appropriate antibiotic for this patient?

   A. cefixime
   B. ciprofloxacin
   C. co-trimoxazole
   D. amoxicillin/clavulanate potassium

Answer Key:

1. B 2. C 3. D 4. C 5. D

SELF-ASSESSMENT EXAMINATION

CCGP offers a Self-Assessment Examination (SAE) to help candidates prepare for the Certification Examination in Geriatric Pharmacy. The SAE is available in an online, Web-based format and in paper-and-pencil, booklet format.

WHO SHOULD USE THE SELF-ASSESSMENT EXAMINATION?

1. • **Candidates** – Evaluate your readiness for taking the proctored certification examination.
2. • **Employers** – Measure your employees' knowledge and skills in geriatric pharmacy practice.
3. • **Pharmacists** – Assess your knowledge and skills in geriatric pharmacy practice.
4. • **Students** – Identify weak areas before completing educational programs to better prepare for licensing examinations.

The SAE consists of 150 multiple-choice questions based on the current Certification Examination content outline. Candidates completing the SAE will receive total scores and a summary of strengths and weaknesses by content area. Both versions of the SAE (Web-based and paper-and-pencil) contain explanations for each correct and incorrect answer, helping you to better understand the reasoning that supports the correct therapy. In addition, the SAEs contain an up-to-date reference list of book and journals that focus on geriatric pharmacotherapy!

For more information about the Web-based SAE, please visit www.ccgp.org and click on the link "Self Assessment Program." To order a copy of the paper-and-pencil SAE, complete the order form in the back of this handbook.

RECOMMENDED REFERENCES

The BCGP Examination Development Committee recommends the following references as useful in learning the basics of geriatric pharmacy practice. This list does not attempt to include all acceptable references, nor is it suggested that the Certification Examination in Geriatric Pharmacy is necessarily based on these references. You should obtain the most current edition available.

General Pharmacotherapy

Applied Therapeutics: The Clinical Use of Drugs. Koda-Kimble MA and Young LY.

Pharmacotherapy: A Pathophysiologic Approach. DiPiro JT, et. al.

Geriatrics

Essentials of Clinical Geriatrics. Kane RL, Ouslander JG, and Abrass IB. New York: McGraw-Hill. ISBN 0-07-033473-0. Available from ASCP. Order phone 800/355-2727. $36.

Merck Manual of Geriatrics. Abrams WB, Beers MH, et.al., eds. Whitehouse Station: Merck and Company. ISBN 0-911910-66-2. Order phone 800/659-6598. $25.

Principles of Geriatric Medicine and Gerontology. Hazzard WR, et.al., eds. ISBN 0-07-027501-7. Available from ASCP, order phone 800/355-2727. $142.50.

Practice Guidelines

The federal Agency for Healthcare Research and Quality (AHRQ) has practice guidelines on pertinent topics, such as heart failure and pressure sores. You may contact AHRQ at 800/358-9295, or on the web at www.ahrq.gov.

The National Guideline Clearinghouse is a web site sponsored by AHRQ that contains hundreds of practice guidelines developed by a wide variety of organizations. This web site is located at www.guideline.gov.

Agenda Item 8

State of California Department of Consumer Affairs

Memorandum

To: **Licensing Committee** **Date: March 1, 2007**

From: **Board of Pharmacy**

Subject: **Licensing Committee Strategic Plan Update**

Last July, the board finalized its strategic plan for 2006-2011. However, each year in the spring, the board revises its plan to keep it current. It is time to start this review.

At this meeting, the Licensing Committee will have the opportunity to revise its strategic plan, if warranted.

At the April Board Meeting, the board will review any modifications to the strategic plan recommended by each committee for development of the 2007-08 strategic plan (completing the annual updating process).

The last activity update of the Licensing Committee's strategic plan follows this page.

LICENSING COMMITTEE

Goal 2: Ensure the qualifications of licensees.

Outcome: Qualified licensees

Objective 2.1	Issue licenses within 3 working days of a completed application by June 30, 2011.
Measure:	Percentage of licenses issued within 3 work days.
Tasks:	1. Review 100 percent of all applications within 7 work days of receipt.

	Apps. Received:				Average Days to Process:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	364*	194**	N	N	9.27	3	N	N
Pharmacist (initial licensing)	532*	312**	N	N	3.5	5	N	N
Pharmacy Intern	559*	539**	N	N	30	30	N	N
Pharmacy Technician	1650*	1044**	N	N	16	16	N	N
Pharmacies	120	92	N	N	10	12	N	N
Non-Resident Pharmacy	7	19	N	N	30	16	N	N
Wholesaler	7	20	N	N	30	30	N	N
Veterinary Drug Retailers	0	0	N	N	0	0	N	N
Designated Representative	93	102	N	N	4	15	N	N
Out-of-state distributors	31	29	N	N	30	30	N	N
Clinics	23	14	N	N	15	13	N	N
Hypodermic Needle & Syringe Distributors	0	4	N	N	10	15	N	N
Sterile Compounding	10	5	N	N	4	7	N	N

**Denotes only October and November 2006 information that was available at time of report development.

*Denotes updated data to include September 2006 information

2. Process 100 percent of all deficiency documents within 5 work days of receipt.

	Average Days to process deficiency:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	10	10	N	N
Pharmacist (initial licensing)	10	10	N	N
Pharmacy Intern	10	10	N	N
Pharmacy Technician	4	5	N	N
Pharmacies	15	2	N	N
Non-Resident Pharmacy	12	15	N	N
Wholesaler	11	10	N	N
Veterinary Drug Retailers	0	10	N	N
Designated Representative	10	10	N	N
Out-of-state distributors	10	10	N	N
Clinics	10	7	N	N
Hypodermic Needle & Syringe	0	6	N	N

3. Make a licensing decision within 3 work days after all deficiencies are corrected.

	Average Days to Determine to Deny/ Issue License:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	1	1	N	N
Pharmacist (initial licensing)	1	1	N	N
Pharmacy Intern	1	1	N	N
Pharmacy Technician	3	3	N	N
Pharmacies	5	4	N	N
Non-Resident Pharmacy	3	1	N	N
Wholesaler	3	5	N	N
Veterinary Drug Retailers	0	2	N	N
Designated Representative	1	2	N	N
Out-of-state distributors	3	5	N	N
Clinics	1	2	N	N
Hypodermic Needle & Syringe	0	1	N	N

4. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements.

	Licenses Issued:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist	532	375	N	N
Pharmacy Intern	524	587	N	N
Pharmacy Technician	2189	1516	N	N
Pharmacies	95	128	N	N
Non-Resident Pharmacy	5	11	N	N
Wholesaler	3	11	N	N
Veterinary Drug Retailers	0	1	N	N
Designated Representative	42	91	N	N
Out-of-state distributors	9	19	N	N
Clinics	27	13	N	N
Hypodermic Needle & Syringe	0	10	N	N
Sterile Compounding	18	13	N	N

5. Withdrawn licenses to applicants not meeting board requirements.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacy Technician	0	11	N	N
Pharmacies	2	4	N	N
Non-Resident Pharmacy	2	13	N	N
Clinics	0	22	N	N
Sterile Compounding	0	0	N	N
Designated Representative	0	0	N	N
Hypodermic Needle & Syringe	0	1	N	N
Out-of-state distributors	0	14	N	N
Wholesaler	2	16	N	N

6. Deny applications to those who do not meet California standards.

Objective 2.2	Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2011.
Measure:	Percentage of cashiered application and renewal fees within 2 working days.
Tasks:	1. Cashier application fees. *1st Qtr 2006:* *The average processing time for processing new application fees is 2-3 working days.* *2nd Qtr 2006:* *The average processing time for processing new application fees is 2-3 working days.* 2. Cashier renewal fees. *1st Qtr 2006:* *The average processing time for cashiering is 2-3 working days.* *2nd Qtr 2006:* *The average processing time for cashiering is 2-3 working days.* 3. Secure online renewal of licenses. *1st Qtr 2006:* *Board meets with programmers to initiate parameters for board licensing programs to convert to DCA Applicant Tracking Program.* *Jan 2007:* *Board converts all application programs to DCA's Applicant Tracking Program. See task 7 below*

Objective 2.3	Update 100 percent of all information changes to licensing records within 5 working days by June 30, 2011.
Measure:	Percentage of licensing records changes within 5 working days
Tasks:	1. Make address and name changes. *1st Qtr 2006:* *Processed 1,832 address changes.* *2nd Qtr 2006:* *Processed 1,322 address changes.* 2. Process discontinuance of businesses forms and related components. *1st Qtr 2006:* *Processed 41 discontinuance-of-business forms. Processing time is 46 days.* *2nd Qtr 2006:* *Processed 0 discontinuance-of-business forms.* 3. Process changes in pharmacist-in-charge and designated representative-in-charge. *1st Qtr 2006:* *Processed 247 pharmacist-in-charge changes. Average processing time is 30 days. Processed 0 designated representative-in-charge changes.* *2nd Qtr 2006:* *Processed 382 pharmacist-in-charge changes. Average processing time is 30 days. Processed 5 designated representative-in-charge changes. Average processing time is 10 days.* 4. Process off-site storage applications. *1st Qtr 2006:* *Processed and approved 42 off-site storage applications. Average processing time is 30 days.* 5. Transfer of intern hours to other states. *1st Qtr 2006:* *Processed 76 applications. Average processing time is 30 days.* *2nd Qtr 2006:* *Processed 45 applications. Average processing time is 30 days.*

Objective 2.4	Implement at least 25 changes to improve licensing decisions by June 30, 2011.
Measure:	Number of implemented changes.
Tasks:	1. Determine why 26 states do not allow the use of a CA license as the basis for transfer a pharmacist license to that state. *Jan. 2007:* *Survey of some states indicate misunderstanding of why California cannot accept NAPLEX scores earned before January 1, 2004. Educational efforts, on a state by state basis, initiated.* 2. Work with the University of California to evaluate the drug distribution system of its clinics and their appropriate licensure. 3. Work with the Department of Corrections on the licensure of pharmacies in prisons. 4. Work with local and state officials on emergency preparedness and planning for pandemic and disasters. Planning to include the storage and distribution of drugs to assure patient access and safety. *Sept. 2006:* *Committee hears presentation by DHS on emergency preparedness.* *Oct. 2006:* *Presentation by Orange County and LA emergency response staff at NABP District 7 & 8 meeting. Board meeting has presentation by DHS and board develops policy statement for licensees in responding to declared emergencies.* *Jan 2007:* *Board publishes disaster response policy statement.* 5. Evaluate the need to issue a provisional license to pharmacy technician trainees. 6. Evaluate use of a second pharmacy technician certification examination (ExCPT) as a possible qualifying route for registration of technicians. *Sept. 2006:* *Committee hears presentation on ExCPT exam approved for certification of techs by five states. Committee directs staff to evaluate exam for possible use in California.* *Dec. 2006:* *Department of Consumer Affairs recruiting for Chief of Examination Resources Office; review postponed. Additional methods to accomplish review considered.* 7. Implement the Department of Consumer Affairs Applicant Tracking System to facilitate implementation of I-Licensing system, allowing online renewal of licenses by 2008. *July 2006:* *Board executive officer becomes executive sponsor of program.* *Nov 2006:* *Board completes system identification of parameters for each licensing program* *Dec. 2006 - Jan. 2007:* *Prepatory work and pilots completed; Board Staff initiates transfer to ATS system as sole platform for applicatn tracking for all licensing programs.*

Agenda Item 9

State of California Department of Consumer Affairs

Memorandum

To: **Licensing Committee** **Date: March 1, 2007**

From: **Board of Pharmacy**

Subject: **NABP Accredits Suppliers of Durable Medical Equipment**

For Information Only:

The National Association of Boards of Pharmacy has been approved by the Centers for Medicare and Medicaid Services to become an accrediting organization for suppliers of durable medical equipment, prosthetics, orthotics and supplies.

According to the NABP, the goal of the program is to ensure that Medicare beneficiaries receive the appropriate products, services, a patient care associated with these items.

A press release describing this program, with questions and answers about this and other NABP certification programs, follows this page.

Licensing

News Release

FOR IMMEDIATE RELEASE

November 29, 2006

For more information contact:
Gertrude Levine, Technical Editor
847/391-4405; custserv@nabp.net

NABP Wins CMS Approval to Accredit Suppliers of Durable Medical Equipment

The National Association of Boards of Pharmacy® (NABP®) received approval on November 22, 2006, from the Centers for Medicare and Medicaid Services (CMS) to become an accrediting organization for suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

NABP's DMEPOS-accreditation program, which meets or exceeds all of CMS' quality standards, targets state-licensed pharmacies that provide a limited line of durable medical equipment. The primary goal of the program is to ensure that Medicare beneficiaries receive the appropriate products, services, and patient care associated with DMEPOS.

"NABP's program is unique because of the Association's extensive knowledge of pharmacy practice and its close tie with pharmacy and the state boards of pharmacy," said Lawrence H. Mokhiber, MS, RPh, NABP president.

NABP's new role as an accrediting organization for DMEPOS suppliers fulfills, in part, Section 302(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which requires the Secretary of Health and Human Services to establish and implement supplier quality standards to be applied by recognized independent accreditation organizations.

(— more —)

As the program is phased in over the next few years, suppliers in designated areas will be required to meet the quality standards and accreditation requirements in order to provide DMEPOS items for which Medicare Part B makes payment, as well as to receive or retain a supplier billing number for use in submitting claims for reimbursement for items or services covered by Medicare.

For more information regarding the DMEPOS program, contact NABP's Customer Service Department at 847/391-4406 or via e-mail at custserv@nabp.net. Program details will be provided on the Association's Web site at www.nabp.net as they become available.

NABP is the independent, international, and impartial Association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

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Licensing

National Association of Boards of Pharmacy (NABP)
Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)
Accreditation Program

Frequently Asked Questions

1. **What is the NABP DMEPOS Accreditation Program?**
It is an accreditation program offered by NABP for licensed pharmacies that distribute certain DMEPOS products and services (listed in Question #9 below) and bill Medicare for these products and services. The NABP DMEPOS Accreditation Program is approved by the US Department of Health and Human Services Center for Medicare and Medicaid Services (CMS).

2. **Is DMEPOS accreditation mandatory?**
Yes, for Medicare. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 mandates that the Secretary of Health and Human Services issue a final rule requiring accreditation and competitive bidding for entities providing DMEPOS, diabetes, and Part B supplies and services.

3. **Must I obtain accreditation to acquire or retain my Medicare Part B supplier billing number?**
Yes.

4. **What happens if my pharmacy does not obtain accreditation?**
Your pharmacy will not be able to competitively bid for DMEPOS products and will not be eligible for reimbursement by Medicare for DMEPOS supplies and services.

5. **Competitive bidding is scheduled to begin in 2007. Do I have to obtain accreditation by January 1, 2007 to continue billing Part B for DEMPOS supplies and services?**
No, but some bidding suppliers will have to obtain accreditation in 2007, others in 2008, and the rest by 2010. Only suppliers from the 10 Metropolitan Statistical Areas (MSAs) selected in 2007 and participating in the competitive acquisition program are required to obtain accreditation, by a yet-to-be determined date in spring 2007. For those suppliers in the first 10 MSAs, to be considered as a bidder, your pharmacy must be accredited by a CMS approved accreditation organization. Bidding suppliers located in the top 10 MSAs will be prioritized by the accreditation organizations.

   5a. What are Metropolitan Statistical Areas (MSAs) and how are they determined?
MSAs are ranked in terms of general population, then scored by the greatest number of suppliers and allowed charges per beneficiary. CMS will select the MSAs. The MSAs that were proposed in the NPRM are:
   - Charlotte-Gastonia-Concord, NC-SC
   - Dallas - Fort Worth – Arlington, TX

- Riverside – San Bernadino – Ontario, CA
- Pittsburg, PA
- Kansas City, MO-KS
- Cincinatti – Middleton, OH – KY – IN
- San Juan – Caguas - Guaynabo, PR
- Cleveland – Elyria – Mentor – OH
- San Francisco – Oakland – Fremont, CA
- Atlanta – Sandy Springs – Marietta, GA
- Houston – Baytown - Sugarland, TX
- Detroit – Warren – Livonia, MI
- Seattle – Tacoma – Bellevue, WA
- Baltimore – Towson, MD
- Philadelphia – Camden - Wilmington, PA- NJ – DE – MD
- Phoenix – Mesa – Scottsdale, AZ
- Boston – Cambridge – Quincy, MA-NH
- Tampa, St. Petersburg- Clearwater, FL

6. **When is my pharmacy required to be accredited?**
The Center for Medicare and Medicaid Services (CMS) will select 10 MSAs in 2007 and 80 MSAs in 2008. The first round will exclude New York, Los Angeles, and Chicago. NABP will prioritize applications from pharmacies located in the first 10 MSAs, which, as of December 19th, had not yet been identified by CMS. However, CMS did inform all the accrediting organizations on December 18th to begin with DME suppliers in Miami, FL. All DMEPOS suppliers, including non-bidding suppliers, must obtain accreditation sometime before January 1, 2010.

7. **Who is eligible to apply for NABP's DMEPOS accreditation?**
NABP's DMEPOS accreditation program is targeted specifically to suppliers who possess a current valid state pharmacy license ***and*** who distribute the DMEPOS products and services listed in question #9 below.

8. **What are my options if my pharmacy carries products or provides services in addition to those listed in question #9 below?**
Such pharmacies may still apply for accreditation with NABP. NABP will establish and maintain relations with other accreditation agencies that have an accreditation focus in areas other than our own. NABP will coordinate with other agencies to complete the accreditation process with these other applicable accreditation agencies.

9. **What products has CMS approved for NABP accreditation?**
   a. Diabetic equipment and supplies, such as:
      - Blood glucose strips;
      - Lancets;
      - Lancet devices;
      - Batteries – replacement;
      - Control solutions;

- Blood glucose monitors;
- Other complementary and related products associated with this group code.

b. Enteral and parenteral nutrients, equipment, and supplies.

c. Orthotics:
- Off-the-shelf orthotics, which are orthotics described in section 1861(s)(9) of the Act that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit a beneficiary;
- Therapeutic shoes and inserts;
- Other non-custom, off-the-shelf and minimally adjustable orthotic items and supplies.

d. Mobility aids that are non-custom and require minimal assistance or self-adjustment:
- Standard walkers;
- Wheeled walkers;
- Crutches;
- Canes;
- Commode chairs stationary fixed;
- Other complementary and related products associated with this group code.

e. Wound care supplies that are non-custom and are generally purchased off-the-shelf, such as:
- Ostomy skin-barrier items and supplies;
- All A codes in ostomy category;
- Collagen-based wound fillers;
- Collagen dressings;
- Code surgical dressing category: tape, gauze pads, hydrocolloid dressing, hydrogel dressing, skin sealant, eye pads, conforming bandages, compression bandages, elastic bandages;
- Other complementary and related products associated with this group code.

f. Urological supplies that are non-custom and are generally purchased off-the-shelf, such as:
- Bedpans;
- Urinals;
- Urinary catheters;
- Incontinence appliances and supplies;
- Other complementary and related products associated with this group code.

g. Medical supplies that are purchased off-the-shelf, such as:
- Heat/cold applications;
- Compression stockings;

- Other complementary and related product associated with this group code.

h. Respiratory – non-custom, off-the-shelf products and supplies:
- Nebulizers;
- Mouthpieces;
- Tubing administration kits;
- Continuous positive air pressure (CPAP) supplies such as, masks humidifiers, head gear, full face masks;
- Other complementary and related products associated with this group code.

10. What is the cost for DMEPOS accreditation?

Single Pharmacy (small supplier)	
New Application Fee (2007)	$345
Annual Participation Fee (2008)	$150
Annual Participation Fee (2009)	$150
NABP Survey*	$1500
Total 3 year cost	$2,145

*Assumption: One surveyor/survey/day

Contact NABP at dmepos@nabp.net for additional information.

11. How do I apply for NABP's DMEPOS accreditation?

Your pharmacy will be able to apply online at NABP's Web site, *www.nabp.net*, as of January 16, 2007.

12. What are the steps required for a pharmacy to become DMEPOS accredited?
- The pharmacy submits an application to NABP along with the required documentation and the specified fee.
- NABP staff verifies pharmacy and appropriate staff licenses.
- NABP staff checks the NABP Disciplinary Clearinghouse for any disciplinary information regarding the facility or pharmacist-in-charge.
- NABP staff evaluates the application, supporting documents, and sample documentation against the CMS Quality Standards.
- Following the documentation review process, NABP communicates with the applicant to request any outstanding documents not submitted with the application, request revisions to any documents that did not meet the Standards, and, if applicable, inform the supplier that NABP will conduct an unannounced, on-site survey.
- NABP conducts an unannounced survey during normal business hours. Refer to question #16 below for specifics regarding the survey process. For applicant pharmacies that carry related products or provide services in addition to those listed in question #9 above, NABP will conduct, whenever practical, concurrent surveys by NABP and other applicable agencies to best meet the needs of CMS, the pharmacy, and NABP.

Please note that if NABP receives information indicating that there is a serious issue of non-compliance with the applicable Standards, NABP may initiate a procedure to deny accreditation to the applicant prior to conducting a survey.

13. Do I need a manual in order to become accredited by NABP?

A manual, per se, is not required. However, all supporting documentation requested with the application must be submitted to NABP for review. NABP believes the pharmacy should have flexibility in crafting a product that suits its needs while at the same time provides NABP with the necessary information to ensure the pharmacy is in compliance with the CMS Quality Standards.

14. What is the time frame for the accreditation process?

NABP's goal is to complete the DMEPOS accreditation process within 30 to 45 calendar days; however, this is dependent on the submitted application materials and operation of the DMEPOS pharmacy. Providing NABP with a complete application and all accompanying documentation will expedite the process.

15. How long is the DMEPOS accreditation valid?

The DMEPOS accreditation is valid for three years. Accredited suppliers will submit a renewal application to NABP every three years. During the three-year cycle, NABP will monitor accredited facilities on an annual basis by: addressing beneficiary complaints, conducting pharmacy and pharmacist disciplinary screenings through our current national Clearinghouse Database, using self-assessment instruments, requiring the suppliers to conduct evaluation surveys of beneficiaries that will be forwarded directly to NABP, and conducting unannounced surveys of suppliers as part of the accreditation process. Unannounced surveys may also be conducted when the accredited facility is suspected of not complying with the CMS standards, or violation of state and/or federal laws,

16. How often will surveys be performed?

NABP conducts an unannounced survey of the accredited DMEPOS-pharmacy once every three years, in accordance with the following comprehensive schedule, to review, evaluate, and monitor the pharmacy supplier, its performance, and compliance with CMS Quality Standards. Complaints (from any beneficiary, regulatory agency, or CMS) and/or a change in critical operations or business structure, such as a change in ownership, could prompt an announced on-site survey at other times.

A. Class I – Independent Community DMEPOS-pharmacy supplier: State License Approved or Renewed and State Board of Pharmacy Inspection Conducted within the Prior 12 Months

a. Review of application and submission materials for the DMEPOS-pharmacy supplier.

b. Review of state board of pharmacy report for applicability of compliance to CMS Quality Standards.

c. If the pharmacy is in compliance with CMS Quality Standards, NABP issues the accreditation and schedules an unannounced survey sometime during the three-year accreditation period.

d. If the pharmacy is not in compliance with CMS Quality Standards, NABP conducts an unannounced on-site survey prior to action on accreditation status.

B. Class II - Independent Community DMEPOS-pharmacy supplier: State License Inspection Greater than 12 Months or a New Pharmacy that has not yet been Inspected

a. Review of application and submission materials for the DMEPOS-pharmacy supplier.

b. Review of state board of pharmacy report, if available, for applicability of compliance to CMS Quality Standards.

c. Unannounced on-site survey, prior to action on accreditation status.

C. Class III – Community Chain (chain defined as four or more DMEPOS-pharmacy suppliers under common ownership) DMEPOS-pharmacy supplier

a. Review of application and submission materials for the DMEPOS-pharmacy supplier designated by the chain to provide DMEPOS.

b. On-site meeting with corporate chain personnel responsible for the DMEPOS-pharmacy suppliers designated by the chain to provide DMEPOS. *(Chain is responsible for the costs associated with this meeting.)*

c. Review of state board of pharmacy reports for applicability of compliance to CMS Quality Standards for the prior year for all DMEPOS-pharmacy suppliers designated by the chain to provide DMEPOS.

d. Review of policies and procedures, corporate quality control, and monitoring systems for the DMEPOS-pharmacy suppliers designated by the chain to provide DMEPOS.

e. Unannounced survey of representative sample and statistically valid number (determined by NABP) of DMEPOS-pharmacy suppliers within the chain designated to provide DMEPOS.

17. What is NABP's procedure for addressing disputes?

The Appeals Procedure is available on the NABP Web site at *www.nabp.net*, under "Accreditation Programs" > "DMEPOS" > "Appeals Procedure."

18. Where can I access the list of accredited DMEPOS pharmacies?

A list of accredited DMEPOS pharmacies is accessible on the NABP Web site at *www.nabp.net*, under "Accreditation Programs" > "DMEPOS" > "List of Accredited Pharmacies."

19. Whom can I contact at NABP regarding DMEPOS accreditation questions?
DMEPOS staff is available at dmepos@nabp.net to answer any questions for which you did not find an answer on our Web site.

20. Does NABP administer other types of accreditation programs?
The Verified Internet Pharmacy Practice Sites™ (VIPPS®) Program
Introduced in February 1999 and supported by the Food and Drug Administration (FDA), the voluntary Verified Internet Pharmacy Practice Sites™ (VIPPS®) program is designed to accredit an online pharmacy that is able to appropriately dispense pharmaceuticals to the public, is licensed in good standing by state boards of pharmacy, has passed a rigorous 18-point criteria review, and has successfully completed an on-site inspection.
The Verified-Accredited Wholesale Distributors® (VAWD®) Program
The Verified-Accredited Wholesale Distributors® (VAWD®) program, supported by the FDA, was established in 2004 to help protect the public from the threat of counterfeit drugs affecting the US drug supply. VAWD accreditation provides assurance that the wholesale distribution facility operates legitimately, is validly licensed in good standing, and is employing security and best practices for safely distributing prescription drugs from manufacturers to pharmacies and other institutions. Applicants for VAWD accreditation undergo a criteria compliance review, licensure verification, inspection, background checks, and screening through NABP's Clearinghouse.
More information regarding NABP's accreditation programs is available on NABP's Web site at *www.nabp.net*.

21. Why should my pharmacy select NABP as the DMEPOS accrediting organization?
NABP has over 100 years of regulatory and accreditation experience in pharmacy. NABP's DMEPOS accreditation services are founded on a long history of fostering uniform quality standards for the practice of pharmacy and the safe distribution of medicines and related supplies. Because of its close ties with pharmacy and its experience as an accrediting organization, accrediting DMEPOS suppliers is a natural extension of NABP's services. In addition to their regulatory expertise, NABP's staff members, several of whom are or have been practicing pharmacists, understand the licensing requirements of pharmacies and pharmacies' operations and resources. NABP staff works with pharmacies to streamline the process and provide for effective accreditation procedures.

22. What are NABP's responsibilities as an accrediting organization?
- Prioritize surveys for those suppliers in the 10 Metropolitan Statistical Areas (MSAs) that need to bid in late 2007.
- Prioritize surveys for those suppliers in the 80 MSAs that need to bid in early 2008.
- Consider any previous accreditation, certification, and/or licensure findings that indicate that DMEPOS quality standards are being met at the time the accreditation organization surveys the supplier.

- Use a streamlined process that considers only compliance with CMS' DMEPOS quality standards.
- Notify CMS, in writing, of any supplier that has had its accreditation revoked, withdrawn, revised, or any other remedial or adverse action taken against it by the accreditation organization within 30 calendar days of any such action taken.
- Notify all accredited suppliers within 10 calendar days of CMS' withdrawal of the organization's approval of deeming authority.
- Notify CMS, in writing, at least 30 calendar days in advance of the effective date of any proposed changes in accreditation requirements.
- Submit to CMS, within 30 calendar days of a change in CMS requirements, an acknowledgement of CMS' notification of the change, as well as a revised crosswalk reflecting the new requirements, and inform CMS about how the organization plans to alter its requirements to conform to CMS' new requirements.
- Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.
- Notify CMS, in writing, within 2 calendar days of a deficiency identified in any accreditation entity where the deficiency poses an immediate jeopardy to the entity's beneficiaries or a hazard to the general public.
- Provide, on an annual basis, summary data specified by CMS that relates to the past years' accreditations and trends.
- Attest that the organization will not perform any DMEPOS accreditation surveys of Medicare participating suppliers with which it has a financial relationship or interest.
- Conform accreditation requirements to changes in Medicare requirements.

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Agenda Item 10

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: Board Members

Date: March 1, 2007

From: Board of Pharmacy

Subject: Competency Committee Report

Test Administration Contract

The Office of Examination Resources (OER) within the Department of Consumer Affairs (DCA) is seeking a new contract with a vendor to provide computer-based testing. The board uses this contract to administer the CPJE. The current contract expired December 1, 2006. OER secured a Noncompetitive Bid (NCB) to continue services with the current contractor through May 31, 2007.

The original procurement method was through a Request for Proposal (RFP) process. The original RFP was cancelled and second RFP was cancelled effective November 8, 2006. The OER Invitation for Bid (IFB) IFB-OER-07-1 for computer-based testing (CBT) was released on December 4, 2006. The RFP procurement method was no longer used as the decision to change the format was made by both the Department of General Services (DGS) and Department of Consumer Affairs (DCA).

The contract was awarded to Psychological Services, LLC (PSI) on February 28, 2007. While there was a protest filed, the contract was awarded as the IFB contained alternate language to move forward and reward the contract should there be a protest. Board staff attended an information-sharing meeting on contract implementation with OER on March 1, 2007. Board staff will be working with the OER on the transition of ending the contract with the current vendor and implementing the contract with PSI.

Given that there will be a new exam vendor potentially (and hopefully) on June 1, there will be transition issues. We have begun working with the California schools and will soon notify all candidates about the changes.

CPJE Statistics

The next CPJE statistical report will cover performance data for 10/1/06-3/31/07. This report should be available at the April board meeting.